



Office de la Propriété
Intellectuelle
du Canada

Un organisme
d'Industrie Canada

Canadian
Intellectual Property
Office

An agency of
Industry Canada

CA 2401596 A1 2001/09/07

(21) **2 401 596**

(12) **DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION**

(13) **A1**

(86) Date de dépôt PCT/PCT Filing Date: 2001/03/01
(87) Date publication PCT/PCT Publication Date: 2001/09/07
(85) Entrée phase nationale/National Entry: 2002/08/29
(86) N° demande PCT/PCT Application No.: GB 2001/000931
(87) N° publication PCT/PCT Publication No.: 2001/064421
(30) Priorité/Priority: 2000/03/01 (0005016.1) GB

(51) Cl.Int.⁷/Int.Cl.⁷ B29C 49/04, A61K 9/48, A61J 3/07,
B29C 49/48

(71) Demandeur/Applicant:
PVAXX TECHNOLOGIES LTD., GB

(72) Inventeurs/Inventors:
STEVENS, HENRY GUY, GB;
DAWSON, JOHN COLIN, GB

(74) Agent: FETHERSTONHAUGH & CO.

(54) Titre : PROCEDE ET DISPOSITIF DE MOULAGE PAR SOUFFLAGE DE CAPSULES D'ALCOOL POLYVINYLIQUE,
ET DE TELLES CAPSULES AINSI PRODUITES

(54) Title: METHOD AND APPARATUS FOR BLOWMODING CAPSULES OF POLYVINYALCOHOL AND
BLOWMOLDED POLYVINYALCOHOL CAPSULES

(57) **Abrégé/Abstract:**

A capsule is formed from a PVA composition by blow moulding. Such capsules can at last provide a viable alternative to gelatin for bio-degradeable capsule containing a pharmaceutical or consumable or other substance, for example a detergent. The capsules may contain solid or liquid substances. Blow moulding apparatus suitable for forming such capsules is also disclosed and claimed.



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 September 2001 (07.09.2001)

PCT

(10) International Publication Number
WO 01/64421 A1

(51) International Patent Classification⁷: **B29C 49/04**,
49/48, A61J 3/07, A61K 9/48 // B29K 29:00

MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL,
TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(21) International Application Number: PCT/GB01/00931

(22) International Filing Date: 1 March 2001 (01.03.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0005016.1 1 March 2000 (01.03.2000) GB

(71) Applicant (for all designated States except US): **PVAXX TECHNOLOGIES LTD.** [GB/GB]; Kemble Business Park, Malmesbury, Wiltshire SN16 9SH (GB).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **STEVENS, Henry, Guy** [GB/GB]; Pvaxx Technologies Ltd., Kemble Business Park, Malmesbury, Wiltshire SN16 9SH (GB). **DAWSON, John, Colin** [GB/GB]; Pvaxx Technologies Ltd., Kemble Business Park, Malmesbury, Wiltshire SN16 9SH (GB).

(74) Agents: **SCHLICH, George, W.** et al.; Mathys & Squire, 100 Gray's Inn Road, London WC1X 8AL (GB).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX,

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG)

Published:

— with international search report
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR BLOWMODING CAPSULES OF POLYVINYLALCOHOL AND BLOW-MOLDED POLYVINYLALCOHOL CAPSULES

(57) Abstract: A capsule is formed from a PVA composition by blow moulding. Such capsules can at last provide a viable alternative to gelatin for bio-degradable capsule containing a pharmaceutical or consumable or other substance, for example a detergent. The capsules may contain solid or liquid substances. Blow moulding apparatus suitable for forming such capsules is also disclosed and claimed.



WO 01/64421 A1

METHOD AND APPARATUS FOR BLOWMODING CAPSULES OF POLYVINYLALCOHOL AND
BLOWMOLDED POLYVINYLALCOHOL CAPSULES

The present invention relates to capsules, particularly biodegradeable capsules and to apparatus and methods for forming such capsules.

There is a demand for biodegradable capsules. Such capsules can contain substances which, on biodegradation or solubilisation of the capsule walls, are released. Speed of release of the substance can be controlled, for example, by varying the thickness of the capsule wall. The demand for such capsules is particularly pronounced in relation to consumable capsules containing, for example, pharmaceutical substances or vitamin or mineral dietary supplements.

It is known to use gelatin to form such capsules for containing liquids. However, there is currently a significant and increasing demand for an alternative to or replacement for gelatin. This demand arises particularly in pharmaceutical applications from patients who are intolerant of gelatin. It is desirable to have an alternative source of material for forming such capsules. Another problem with gelatin capsules is that they are not generally suitable for containing dry or powdered substances.

A suitable substitute for a gelatin capsule not only must be biodegradable, in certain applications it must be edible and have an inoffensive taste, and it must of course be readily formable into capsules. The potential market for a suitable substitute for gelatin is major and various alternatives have been tried over many years but all suffer from various drawbacks. Also known are two-part capsules; these may impose different constraints on the material properties and are generally suitable only for containing powdered or dry substances. They are less suited to containing liquids and the two-part construction may lead to complications in forming

and filling and/or may mean that the contents are not hermetically sealed.

The invention seeks in a general aim to provide a viable alternative to gelatin capsules.

In a first aspect, the invention comprises a capsule having walls formed, most preferably by blow moulding, from a PVA containing composition and containing a substance.

PVA has not hitherto been commercially manufactured into capsules containing a substance due to the well known and established conventional properties of PVA. However, the inventor has found that by making use of a PVA composition provided as a polymer feedstock in the form of a cold pressed compounded tablet or pellet, surprisingly reliable formation of such articles as capsules can be consistently achieved and thus PVA can surprisingly be used successfully in this novel application.

The capsule is most preferably sealed; this may prevent deterioration of the substance. The substance may be consumable. Particularly if the substance is consumable, the PVA composition may contain exclusively food grade ingredients. The PVA composition may contain a filler which is inert or consumable, for example calcium carbonate and/or a plant or vegetable derivative product, such as wood flour or rice husk.

The substance may be substantially solid, dry or powdered. The invention is particularly useful for facilitating provision of a sealed (one part, substantially unitary) capsule containing a solid substance. Hitherto, it has not been practicable to supply powdered substances encapsulated in sealed capsules on a large scale and the invention may surprisingly facilitate this.

The invention is particularly advantageous when applied to small capsules, for example having a volume of less than about 5 cm³, more typically less than about 1 cm³, often about 0.5 cm³.

In a preferred embodiment, the invention provides a sealed capsule blow
5 moulded from a PVA composition containing exclusively food grade ingredients and containing a consumable substance.

As noted above, most preferably the capsule is formed by blow moulding; this provides a surprisingly convenient means of reliably forming capsules. Historically, applications of PVA have been limited because of difficulties encountered in melt
10 extruding it: namely, that melt extruded PVA becomes very unstable and significant residues become adhered to the extrusion apparatus; that very careful control of process conditions and specialised apparatus are required; and that the process has to be shut down and the apparatus purged frequently. Because of this unreliability, PVA has not generally been considered a suitable candidate for blow moulding in
15 general as non-uniformities may lead to rupture of the film. In a relatively small and delicate capsule which may need to contain an accurately measured quantity of substance such problems would be even more severe. However, surprisingly, if the PVA has been compounded and cold-pressed as described herein it can be reliably melt-extruded into a blow-moulding apparatus, such as described herein, for forming
20 capsules. These compositions may have similar mechanical properties to gelatin and may be edible, having an inoffensive taste. These compositions can thus successfully be used to substitute gelatin.

Apart from choice of a suitable material, there are several problems associated with blow moulding to a high standard of quality in a cost efficient

manner. Extrusion blow moulding is a technique that is normally used for moulding hollow plastic articles such as bottles from thermoformable polymers. Conventionally the thermoformable polymer is first heat extruded into a preform or parison. Then a two part moulding die is closed around the preform. If the thermoformable polymer is too viscous for this to be feasible, the two part moulding die is first closed and the heat extruded thermoformable polymer is injected into it. Air is injected into the preform to expand the preform against the mould cavity. The preform is thus blow moulded into the shape of the cavity of the die. The mould is then opened/separated and the blow moulded article is removed. One of the problems is the minimisation of the cycle time to produce a moulded article. Embodiments of the present invention provide an apparatus including a mould arrangement that enables the blow moulding of a PVA composition to a reliable standard while minimising cycle time.

A second aspect of the present invention provides an apparatus for blow moulding a PVA composition into a capsule, the apparatus comprising means defining at least one moulding cavity, preferably a plurality of moulding cavities, means for injecting a PVA composition into each moulding cavity, preferably substantially simultaneously, means for inflating the PVA composition in each moulding cavity to form a capsule, means for filling each capsule with a substance and means for sealing each filled capsule.

The means defining a plurality of moulding cavities may comprise a mould made up of separable parts and preferably comprises a mould having two halves. If the mould comprises two halves, each mould half contains a series of respective recesses so that, when placed together, both halves form a mould comprising a row

-5-

of cavities suitable for forming capsules. If the mould is made up of more than two separable parts, the parts should be such that, when placed in position together, they form a mould comprising a row of cavities suitable for forming capsules. Preferably the mould has at least about 10 cavities. The mould may have more, for example about 20 or about 30, cavities in a row. Typically the cavities will form capsules having a volume of less than 5 cm^3 , more typically less than about 1 cm^3 , often about 0.5 cm^3 . Typically, the process involves bringing the mould parts (halves) together, injecting the heat extruded PVA composition into each mould, inflating the PVA composition in each mould to form a capsule, filling each capsule with a substance and sealing each filled capsule.

The use of the mould arrangement of the present invention i.e., the means defining a row of moulding cavities, enables the successive injection, inflation, filling and sealing of a number of capsules with just one act of placing of the mould parts (halves) together and one act of separation of the mould halves, thus minimising the number of times the mould parts (halves) have to be brought together and separated per formation of one filled capsule. Thus the cycle time to produce a moulded article is minimised. In the process of the present invention it is preferred that the step of filling is carried out so that the capsules are filled in quick succession. This may ensure consistent batches of capsules. For pharmaceutical applications in particular, the consistency and accuracy of the measured amount of filling is very important. Preferably the step of PVA injection is carried out for all of the cavities in quick succession, for example by moving the mould with respect to an injection source, or substantially simultaneously.

The apparatus may comprise physically separate stations for some or all of

the steps of injection, inflation, filling and sealing. The apparatus may also comprise translation means for moving the mould form one station to another.

A suitable pressurised fluid, normally gas, may be used for inflating the PVA composition. Usually such means utilise compressed air. In a preferred embodiment of the present invention an inert gas such as nitrogen or argon is used to inflate the PVA composition. The capsule then contains a substantially inert atmosphere prior to filling with the substance. This has the advantage of minimising exposure of the substance to air. This is of particular importance for substances that are sensitive to air and/or that oxidise readily.

An injection nozzle may be used for filling the capsule. The capsule may be filled with a substance which may be in the form of a liquid or a powder. Previously gelatin capsules were generally used to contain only liquids and powdered medicaments were contained in two-part capsules. Therefore it is another surprising advantage of this invention that it produces a sealed, substantially one-part capsule that is suitable for containing powder. One-part capsules are more air tight than two-part capsules. One-part capsules are better for controlled-release applications as the thickness of the capsule walls is more even.

Although the capsules of the present invention are suitable for pharmaceutical applications, e.g. for containing pharmaceutical substances such as medicaments and suitable for containing dietary supplements such as vitamins, minerals and edible oils, they may also be used in other applications that require the (controlled) release of a substance by means of biodegrading or solubilising a capsule wall. An example of such another application is that of capsules containing bubble bath or bath oil. A further example is a capsule containing a detergent

powder or liquid, for example for use in a dishwasher or washing machine. Such capsules may have a larger capacity, for example up to 10 cubic centimetres or even larger. A detergent dispenser, for example for a dishwasher or washing machine, comprising a quantity of detergent (liquid or powdered) in a soluble capsule formed from a PVA composition, preferably a cold-water soluble composition (optionally a warm or hot water soluble composition) may be provided independently according to a further aspect of the invention.

Preferably the sealing is done by means of a knife. Preferably the knife is heated and is passed over the top of the capsule thereby sealing the top of it. The mould arrangement is such that more than one capsule can be sealed by the same passing stroke of the knife. This is therefore a particularly fast, clean and efficient way of sealing the capsules. This sealing method helps minimise the exposure of the substance contained in the capsule to air. This is particularly important for substances which are sensitive to air and/or oxidise easily. The mould parts (halves) are then separated and the filled capsules released.

Further aspects and preferred features are set out in the claims.

An embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a generalised schematic diagram of apparatus according to an embodiment of the invention

Figure 2 shows a schematic front view of a capsule forming cavity;

Figure 3 shows schematic side view of a capsule forming cavity showing the opposed mould halves;

Figure 4 shows a front view of blow moulding apparatus having a plurality of

moulding cavities;

Figure 5 shows a section through the apparatus of Fig. 4.

In the figures, like parts are designated by like reference numerals.

Referring to Fig. 1, a supply of PVA pellet feedstock 1 is provided via a supply
5 hopper 10 (or other suitable feeding arrangement) to a melt extruder 12 which may
comprise a screw type extruder as typically used to extrude conventional
thermoplastics, the output of which is supplied to blow moulder 14. The blow
moulder has a plurality of moulding cavities 15, to be described further below, in
which capsules are formed and receives a supply of compressed gas 16 and a
10 supply of a substance to be encapsulated 2 via a metering device 18. In the
embodiment shown, the substance is a pharmaceutical but other substances may
be used, for example detergents. Although the apparatus is shown as separate
parts, the functions may be integrated, in particular the function of the metering
apparatus is conveniently integrated into the portion of the blow moulder which fills
15 the capsules. The blow moulder ejects filled capsules 22 into a suitable container
20.

Referring to Figs. 2 and 3, a mould 30 formed from opposed mould halves
30a, 30b provides a plurality of cavities in the shape of the capsule desired. A
single ellipsoidal cavity 15 is shown in Fig. 2. A more complex shape may be
20 formed and this may incorporate a logo, for example. A thin wall of PVA
composition 31 is formed within the mould cavity from an injected stream 36 of PVA
derived from melt extruder 12. Whilst in some cases the polymer may be directly
injected into the cavity, more preferably a preformed section of polymer, typically
tubular, is extruded and this section is trapped between opposed mould halves,

closure of the mould halves sealing an end. The capsule is inflated by means of compressed gas injected through nozzle 32 opposite the trapped end so that it fills the cavity and liquid or powdered substance to fill the capsule may be injected by means of needle 34. The needle must be of sufficient bore to permit liquid to flow under the conditions of liquid viscosity and pressure expected. Similarly, for powdered substances, the bore must be sufficient to avoid clogging. Such considerations are well known to those skilled in the art of filling medicament capsules and it will be appreciated that problems may be alleviated by enlarging the injection orifice or increasing injection pressures, or by reducing particle size or viscosity, for example by processing solids or by adding diluents to liquids.

After injection of the substance, the needle is withdrawn and the capsule is preferably sealed. If the polymer is sufficiently molten and the needle sufficiently small, the capsule may self seal. More preferably, to ensure reliable sealing, a heated knife or other implement is drawn across the capsule in the region of the needle opening to cause local melting and sealing of the capsule. Excess not cut off directly by the action of the mould halves coming together or by the sealing knife may be trimmed, although normally a seam will remain. A visible seam can provide an assurance that the capsule integrity remains and this may be useful in the case of a pharmaceutical or consumable capsule and may be provided for decorative or advertising purposes in other cases. The invention independently provides a sealed capsule, particularly a pharmaceutical, formed from PVA containing a substance and having a seam.

Figs. 4 and 5 show an example of a practical mould embodying the principles shown in the schematic figures. This example shows a single needle assembly 39

used for injecting polymer, air and substance. A row of needle assemblies can be used to fill a row of capsules simultaneously or a single needle assembly, or smaller number of needle assemblies may be used to fill a proportion only of the cavities and translated relative to the mould to complete the process of filling all cavities.

5 The substance may be injected by means of a needle separate from the assembly that supplies the polymer. Not shown, the mould is preferably provided with cooling to ensure more rapid solidification of the injected polymer. Multiple rows of multiple capsules may be supplied from a single extruder; as will be appreciated, the greater the number of mould cavities, the greater the rate of capsule production that can be
10 achieved. The invention can be applied to a mould having a single cavity. However, whilst not excluded, this is less preferred for capsule formation due to the larger cycle time required; a particular advantage is provided by the use of a mould defining a plurality of cavities.

The PVA-containing composition used to form the feedstock 1 in the
15 embodiments is in the form of cold-pressed pellets or tablets and preferably comprises a blend of PVA and an amount of lubricant effective to render the blend extrudable. The lubricant preferably comprises a fatty acid amide or a plasticiser or a mixture of both a fatty acid and a plasticiser, the resultant blend being suitable for extrusion in conventional melt-extrusion apparatus. The composition typically has
20 a flexural modulus similar to other extrudable polymers. Known advantageous properties of PVA, such as high tensile strength, good puncture resistance and good barrier characteristics are retained in this composition.

Preferred feedstock comprises a PVA-containing composition comprises up to 20%, especially 5 to 15%, plasticizer and up to 5%, especially 0.5 to 2.5%,

lubricant, by weight.

In embodiments of the invention, extrudable and blow mouldable PVA-containing compositions have been obtained comprising fully hydrolysed PVA as well as partially hydrolysed PVA, and including PVA that is 70% or more hydrolysed.

5 The PVA-containing compositions may have a molecular weight of the PVA varying from around 20,000, in some cases from around 10,000, to greater than 150,000. Generally, the application of the present invention is not limited to PVA of any particular percent hydrolysis nor of any particular molecular weight.

10 The lubricant composition of the invention is provided so as to improve the thermal instability of the composition under extrusion. The lubricant may be referred to as an internal lubricant, in that its function is to improve lubrication between the polymer chains.

15 Compositions of the invention may be intended for consumption and hence it is preferred that the lubricant is approved for this purpose. It is further preferred that the lubricant is a fatty acid amide, and particularly a straight or branched C_{12} - C_{24} fatty acid amide, more particularly C_{16} - C_{20} . Particularly and surprisingly good results are obtained if the lubricant comprises stearamide, a straight chain C_{18} fatty acid amide.

20 The compositions of the invention typically further include a plasticiser, to lower the melt temperature of the polymer under extrusion. The plasticiser may suitably be selected from glycerine, ethylene glycol, triethylene glycol, low molecular weight polyethylene glycols and low molecular weight amides. A particularly preferred plasticiser comprises or consists of glycerol.

While the proportion of components present may vary in compositions of the

-12-

invention, embodiments of the invention generally comprises, by weight, up to 50% filler and up to 5% lubricant. More particular embodiments of the invention comprise, by weight, 5-50% filler, 40-80% PVA, up to 5% lubricant and 5-20% plasticiser.

- 5 Good results have been obtained with embodiments having the following make up, by weight:-
- (a) 40 to 80% PVA;
 - (b) 5 to 50% filler;
 - (c) 5 to 15% plasticiser, preferably glycerol;
 - 10 (d) 0.5 to 2.5% lubricant, preferably a fatty acid amide as an internal lubricant, most preferably octodecanamide.

Particularly good results have been obtained in embodiments of the invention having the following make up, by weight:-

- (a) 40 to 70% PVA;
- 15 (b) 20 to 50% filler, preferably a micronised inorganic material such as talc, preferably coated with stearate;
- (c) 8 to 15% plasticiser, preferably glycerol;
- (d) 0.5 to 1.5% internal lubricant, preferably a fatty acid amide, most preferably octodecanamide; and
- 20 (e) 0.0001 to 0.1% external lubricant, preferably stearate.

The composition may contain residual moisture, sufficient to enable the composition to be bound as a cold-pressed tablet.

Exemplary compositions which may be employed for the feedstock will now be

detailed.

Example 1

5 A blend of, by weight, approximately 60% fully hydrolysed PVA, 30% calcium carbonate, 10% glycerol, 0.01% zinc stearate and 1% octadecanamide was prepared in a high speed blender. It was found to have a white/cream colour with the following properties:-

10	density	1.65 g/cm ³
	melt density	1.46 g/cm ³ at 200°C (under ISO 1183)
	MFR	357 (10 mins/200°C/21.6 kilograms, under ISO 1133)
	melt temperature	200°C
15	processing temperature	190 - 200°C
	residence time	up to 15 minutes
	drying time	4 hours at 80°C

Example 2

20

A blend was prepared in a similar way to example 1 of, by weight, approximately 60% partially hydrolysed PVA, 30% calcium carbonate, 10% glycerol, 0.01% zinc stearate and 1% octadecanamide. This was found to have the following properties:-

WO 01/64421

PCT/GB01/00931

-14-

density	1.65 g/cm ³
melt density	1.38-1.40 g/cm ³ at 190°C (under ISO 1183)
MFR	22 (10 mins/190°C/5 kilograms, under ISO 1133)
apparent melt viscosity	236/49 (Pa.s 1,000s/10,000s)
melt temperature	200°C
processing temperature	190-200°C
residence time	up to 15 minutes
drying time	4 hours at 80°C

) The compositions of both examples 1 and 2 were satisfactorily extruded and blow moulded.

Example 3

5 The PVA-containing compositions of examples 1 and 2 were examined for their extrudability in injection-moulding machines made by Brabender, Killion, Windsor, Hesas, Battenfield, Fischer, Demag and Arburg. Extrusion processing was carried out using a single full flight screw with constant pitch. The barrel temperature had a profile of 180-200°C (melt 190-210°C) and the screw speed varied typically between 20 and 120 rpm. Shut down of the apparatus was carried out by
0 maintaining the temperature for up to 15 minutes with screw rotation stopped, over a period of 3 hours reducing the temperature to 100°C with screw rotation stopped and subsequently completing the shut down by turning the machine off.

Whether or not a given composition is extrudable (by which is meant on

commonplace extrusion apparatus) will normally be clear to one skilled in the art.

In the event that a test is required, however, it is suggested that extrudability is determined by attempting extrusion on one or more of the above-named manufacturers machines using a single full flight screw with constant pitch with speeds and temperatures in the above range. If the composition extrudes reliably on at least two of the above machines with routine adjustment of parameters, it is to be deemed extrudable; if consistent problems are obtained and extrusion is only possible under highly specific conditions or on specialised equipment, it is to be deemed not to be extrudable.

Examples 4-9

PVA-containing compositions were prepared as blends of the following components in the amounts shown:-

EXAMPLE						
	4	5	6	7	8	9
<u>Components</u>						
PVA - fully hydrolysed	-	-	-	50	60	55
PVA - partially hydrolysed	50	60	55	-	-	-
Calcium carbonate (coated)	40	30	30	40	30	30
Glycerol	9	9	14	9	9	14
Octadecanamide	1	1	1	1	1	1
Zinc Stearate	0.01	0.01	0.01	0.01	0.01	0.01

-16-

As far as extrusion apparatus is concerned, it is advantageous to use chrome plated screws and for the melt flow path to use chrome plated surfaces and gradual tapers to streamline the melt.

As an alternative to calcium stearate as a filler, organic substances such as rice husk and wood flour may be used.

Embodiments of the invention thus provide capsules formed from PVA-containing compositions which are bio-degradable.

Aspects of the invention may further provide independently or in combination any one or more of the preferred or optional features disclosed herein and/or any one or more of (i) use of a PVA composition in the manufacture of a capsule (ii) a sealed blow-moulded PVA capsule containing a powdered substance (iii) a pharmaceutical composition contained within a PVA capsule (iv) a method of sealing a blow moulded PVA capsule containing a substance comprising melting a portion of the capsule and (v) use of PVA in the manufacture of a consumable capsule containing a medicament for the treatment of a condition in a patient averse to consumption of gelatin. In preferred applications, particularly pharmaceuticals and food supplements, the PVA composition is preferably cold-water soluble. In detergent dispenser applications, the solubility temperature may be selected to provide controlled or delayed release. In certain applications, for example paintball capsules, hot water soluble PVA may be used. The appended abstract is incorporated herein by reference. Reference numerals appearing in the claims shall have no limiting effect.

CLAIMS

1. Apparatus for forming a sealed filled capsule having walls formed from a PVA composition which apparatus comprises means defining a plurality of moulding cavities, means for injecting a source of PVA composition into each moulding cavity, means for inflating the PVA composition in each moulding cavity to form a blow moulded capsule, means for filling each capsule with a substance and means for sealing each capsule.
2. Apparatus according to claim 1 in which said sealing means comprises a knife arranged to be heated and swept across the top of each capsule.
3. Apparatus according to claim 1 or claim 2 in which the inflating means comprises means for injecting a gas.
4. Apparatus according to claim 3 wherein gas is an inert gas, preferably nitrogen or argon.
5. Apparatus according to any preceding claim, further comprising means for dispensing a measured amount of substance into each capsule.
6. Apparatus according to Claim 5 including means for determining the mass of substance dispensed.
7. Apparatus according to Claim 5 or 6 including means for determining the

volume of substance dispensed.

8. Apparatus according to any of Claims 5 to 7 including a pre-dispensing chamber of defined dimensions for storing a measured amount of substance prior to dispensing into the capsule.

9. Apparatus according to any preceding claim arranged to dispense a powdered substance into the capsule.

10. Apparatus according to any of Claims 1 to 8 arranged to dispense a liquid substance into the capsule.

11. Apparatus according to any preceding claim having a plurality of injection means for filling a plurality of the moulding cavities substantially simultaneously.

12. Apparatus according to Claim 11 wherein an injection means is provided for each cavity.

13. Apparatus according to Claim 11 wherein at least some injection means are arranged to fill a plurality of cavities sequentially.

14. Apparatus according to any of Claims 1 to 10 having a single injection means arranged to fill the cavities sequentially.

-19-

15. Apparatus according to any preceding claim wherein a number of cavities are at least partially defined by substantially adjacent recesses formed in an integral mould block.
16. Apparatus according to any preceding claim wherein the cavities are defined by opposed recesses in opposed mould halves.
17. Apparatus according to any preceding claim including control means for controlling a repetitive cycle in which the cavities are sequentially formed, filled with PVA polymer and inflated, filled with the substance, sealed and ejected from the mould.
18. Apparatus according to any preceding claim including means for receiving a supply of melt-extruded PVA from a melt extruder.
19. A system according to Claim 18 further comprising said melt extruder.
20. A system according to Claim 19 wherein said melt extruder is arranged to receive a supply of cold-pressed compounded PVA pellets.
21. A system according to Claim 20 further comprising said supply of cold-pressed compounded PVA pellets.
22. A system according to Claim 21 wherein said cold-pressed compounded PVA

pellets comprise a blend of PVA and up to 5% lubricant by weight to render the blend extrudable.

23. A system according to any preceding claim further comprising means for receiving a supply of said substance.

24. A system according to Claim 23 including a supply of said substance.

25. A system according to Claim 24, wherein said substance is consumable, preferably a pharmaceutical.

26. A system according to Claim 25 as dependent on Claim 22 wherein said PVA containing composition contains exclusively food-grade components.

27. A system according to any preceding claim further comprising a batch of filled sealed PVA capsules containing said substance produced by the apparatus.

28. A sealed PVA capsule containing a substance, produced by the apparatus of any preceding claim.

29. A capsule having walls formed from a PVA containing composition and containing a substance.

30. A capsule according to Claim 29 formed by blow moulding.

-21-

31. A capsule according to Claim 29 or 30 wherein the capsule is sealed.
32. A capsule according to any one of Claims 28 to 31 wherein the substance is consumable.
33. A capsule according to Claim 32, wherein the PVA composition contains exclusively food grade ingredients.
34. A capsule according to Claim 33, wherein the PVA composition contains a filler which is inert or consumable.
35. A capsule according to any of Claims 28 to 34 wherein the substance is substantially solid.
36. A capsule according to any of Claims 28 to 34 wherein the capsule has a volume of 5 cubic centimetres or less.
37. A capsule according to any of Claims 28 to 35 wherein the capsule contains a measured dose of a pharmaceutical substance.
38. A capsule according to any of Claims 28 to 36 wherein the capsule contains a detergent.
39. A capsule according to any of Claims 28 to 38 wherein the capsule is formed

-22-

from a PVA composition comprising by weight:-

- (a) 40 to 80% PVA;
- (b) 5 to 50% filler;
- (c) 5 to 15% plasticiser, preferably glycerol;
- (d) 0.5 to 2.5% lubricant, preferably a fatty acid amide as an internal lubricant, most preferably octodecanamide.

40. A process for producing filled capsules comprising forming said capsules from a polyvinyl alcohol composition which process utilises the apparatus of any one of Claims 1 to 29.

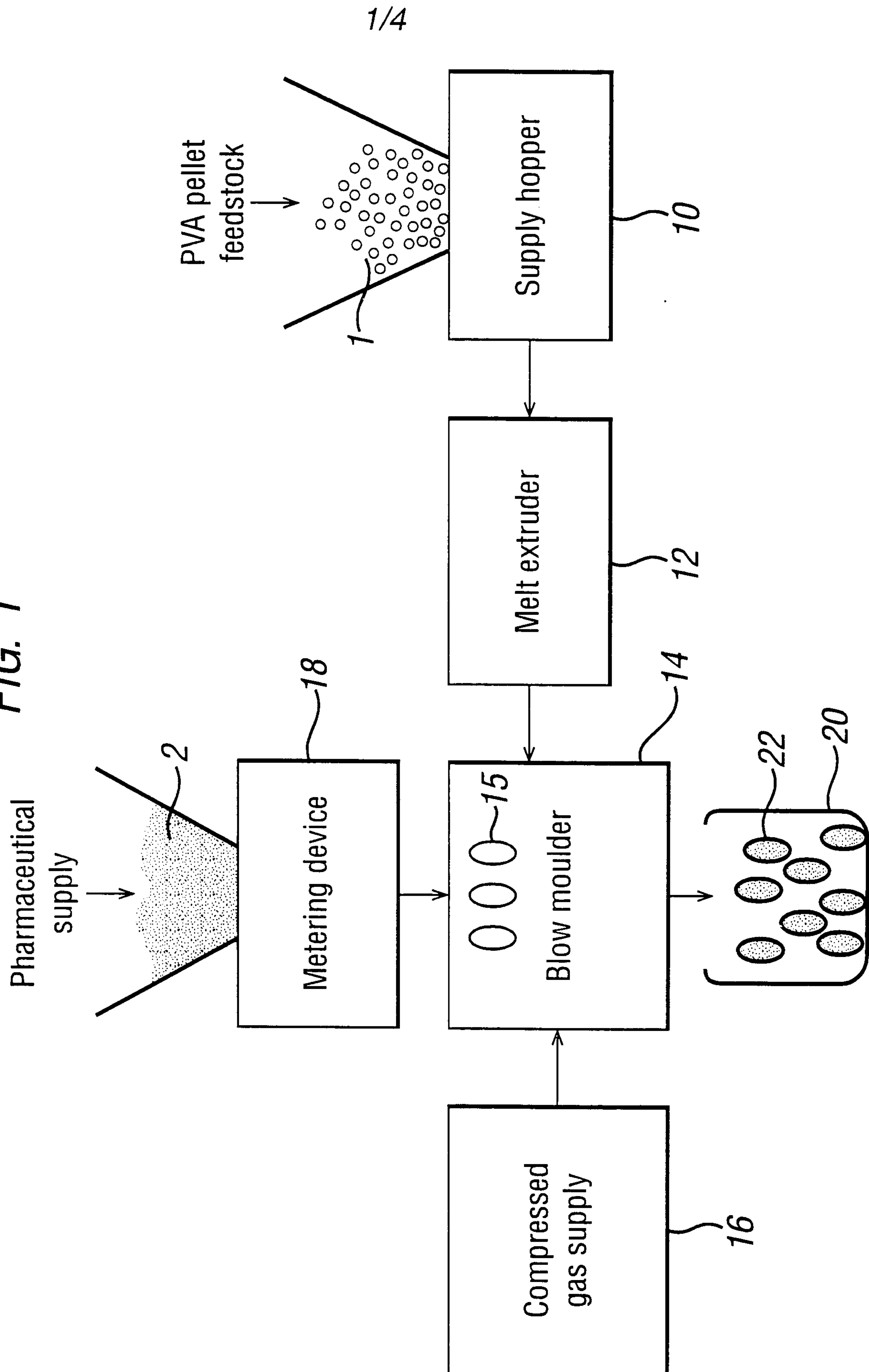
41. A process for forming a filled capsule comprising:
receiving a supply of cold-pressed compounded PVA pellets;
melt extruding the cold-pressed pellets to form PVA feed for blow moulding;
injecting the PVA feed into a mould defining a plurality of cavities;
inflating the PVA within each mould cavity to form a blow-moulded capsule;
filling the capsule with a substance;
sealing the capsule;
ejecting the filled capsule.

42. A process according to Claim 40 or 41 wherein the substance with which the capsule is filled is a pharmaceutical substance.

-23-

43. A process according to any one of claims 40 to 42 wherein the substance with which the capsule is filled is in powder form.
44. A capsule obtained by the process according to any one of claims 40 to 43.
45. A pharmaceutical comprising a sealed capsule formed from a PVA composition, the capsule containing a dose of medicament.
46. A food supplement comprising a dose of at least one vitamin or nutrient encapsulated in a PVA composition.
47. A detergent dispenser comprising a detergent encapsulated in a capsule formed from a PVA composition.
48. A sealed capsule containing a powdered substance, the capsule formed by blow moulding from a PVA composition.
49. A capsule substantially as any one herein described.
50. Apparatus for forming a PVA capsule substantially as herein described or as illustrated in the accompanying drawings.
51. A process for forming a capsule substantially as herein described.

FIG. 1



2/4

FIG. 2

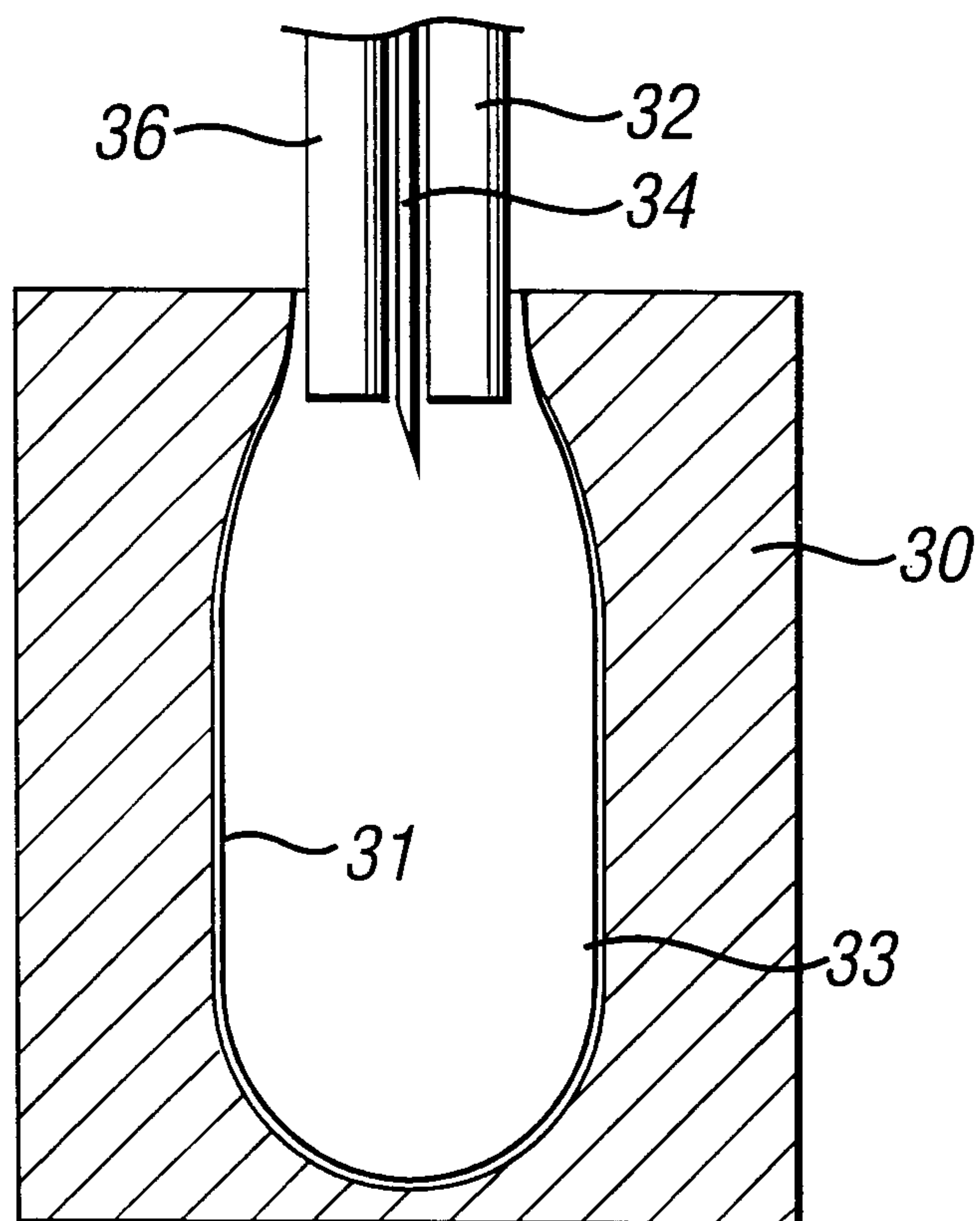
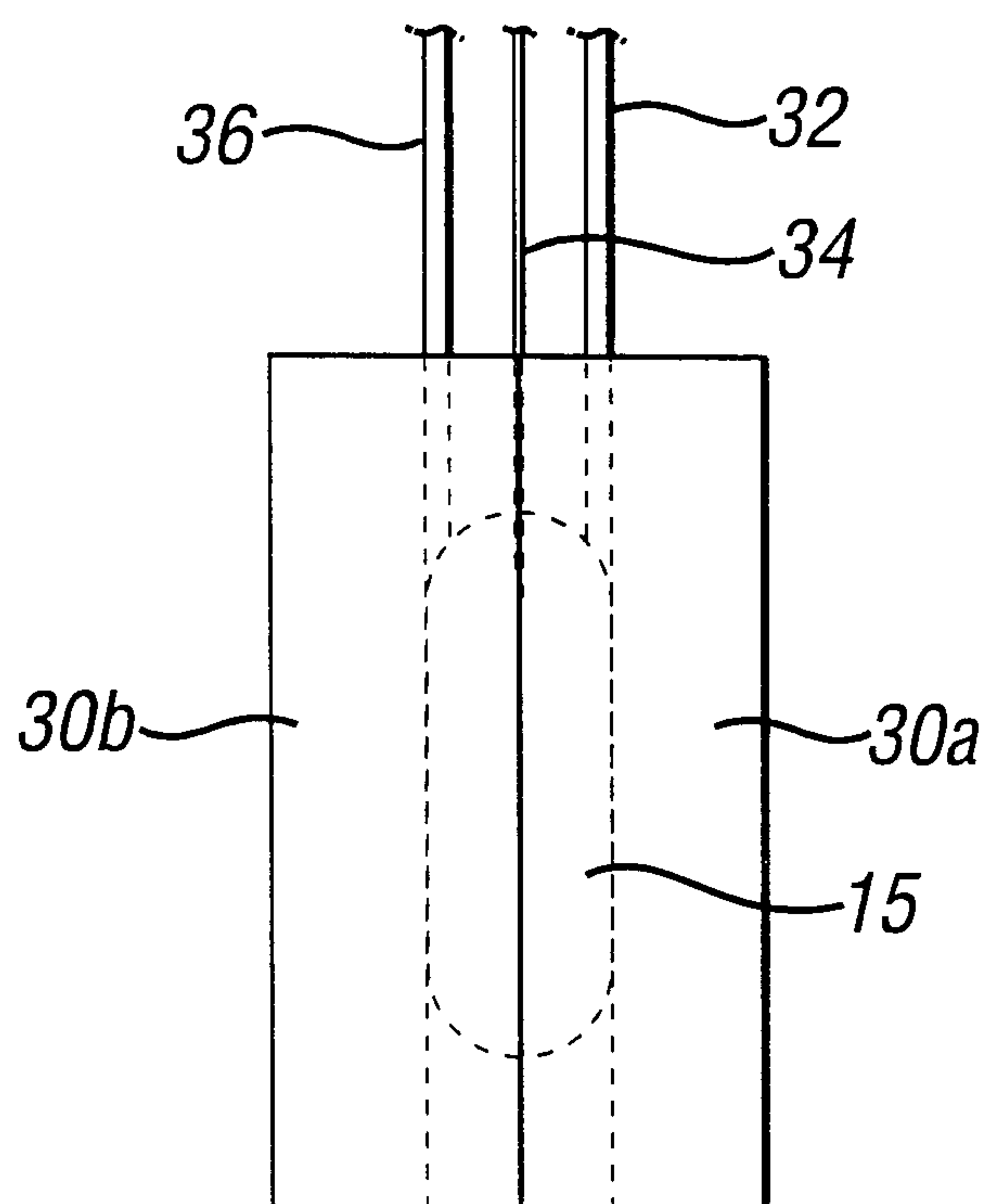


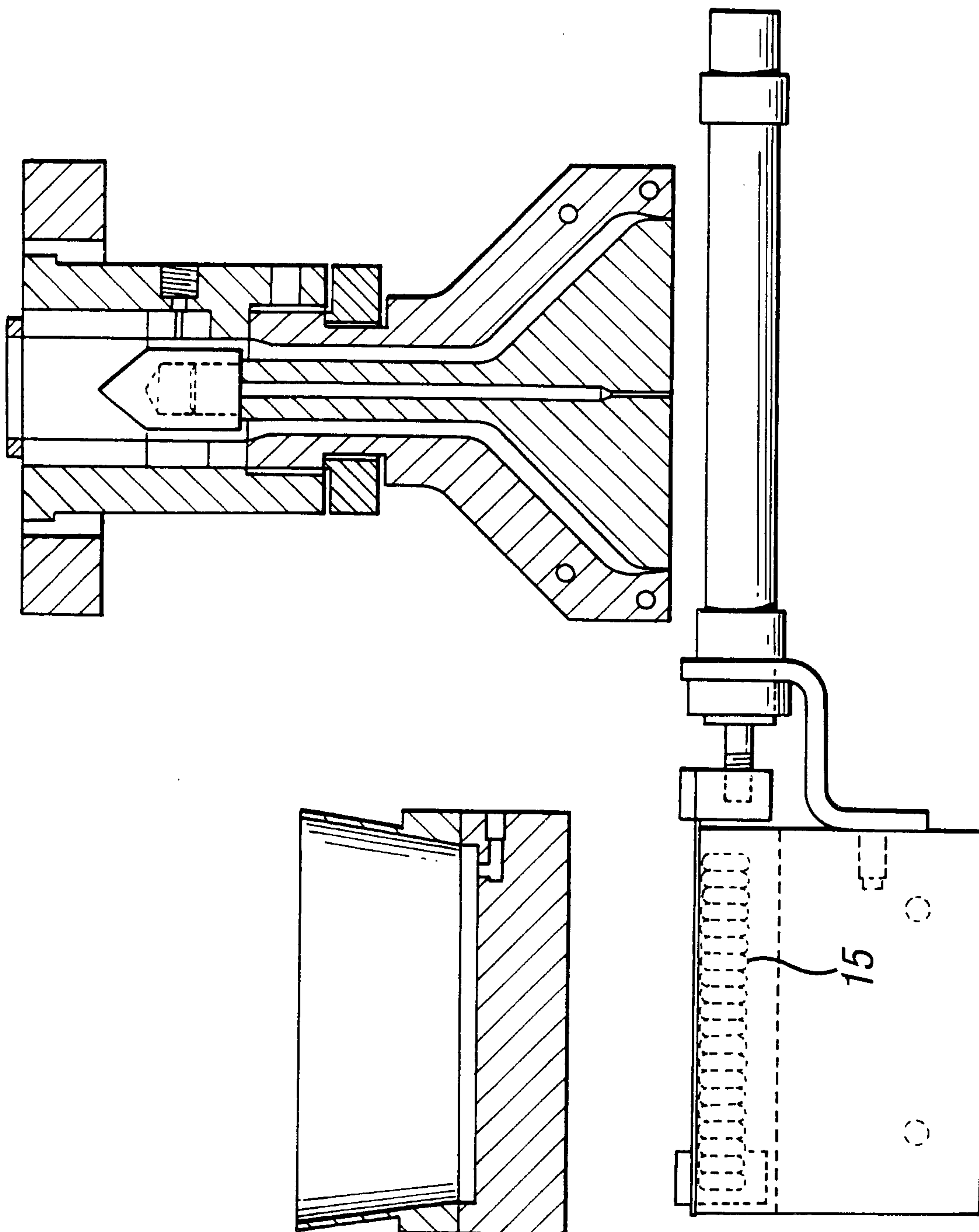
FIG. 3



3/4

top of jaws

FIG. 4



4/4

FIG. 5

