PATENT AGENT EXAMINATION, 2013 (Under Section 126 of the Patents Act, 1970)

4th May 2013

PAPER II

Total Marks: 100 Time: 2.30 p.m. to 5.30 p.m.

Three hours

Instructions:

- 1. This paper consists of 2 parts Part A (40 marks) & Part B (60 marks).
- 2. ALL questions in Part A are compulsory.
- 3. Part A consists of 4 questions of 10 marks each.
- 4. Part B comprises two sections Part B1 and B2, of 30 marks each. Part B1 consists of 2 questions and you are required to answer any 1 of them. Part B2 also consists of 2 questions and you are required to answer any 1 of them. In case a candidate answers more questions than required, the first attempted question will be evaluated.
- 5. Candidates should read the questions very carefully before answering.
- 6. No clarification will be provided during the course of the examination.
- 7. There is no negative marking.

PART A

 $4 \times 10 = 40 \text{ marks}$

- 1. Rupa, a textile designer with a 'Design House' in Mumbai having branch offices in various parts of the world, wishes to obtain patent protection in 50 different countries for smart textiles invented by her. Foreign buyers prefer to deal with inventor/applicants who have filed their patent applications in Europe as basic applications i.e. the first application to be filed on the subject matter. She also wishes to file a set of patent applications in Europe with varying priority dates. Rupa has approached you as her Patent Agent in India to help her in her mission. Provide a note to her outlining the strategy she ought to follow alongwith information on various processes / routes involved and the timelines involved. How would you also deal with the multiple priorities?
- 2. Korobi Sen in Kolkata has worked on the development of special sweet compositions for diabetic patients. These compositions also contain some herb extracts. The sweets developed by her have very special properties in that the blood sugar levels do not rise when these sweets are consumed. She has filed a patent application in the Patent Office, Kolkata claiming the compositions for her sweets and the method of making them. The Controller issued an examination report objecting to the grant of the patent by citing Sections 3(e), 3(i) and 3(p) of the Indian Patents Act. Korobi has approached you to respond to the first examination report (FER) and also to attend a

hearing at the Patent Office in due course. Draft a response to the objections raised in the FER.

- 3. Anjan has been involved in the development of drainage systems. He thought it necessary to conduct tests in the compound of his large housing society to assess the scalability of his newly developed drainage system on 30th March 2009. On 1st September 2009, Anjan applied for a patent in the Mumbai Patent Office. Anjan was very confident that there was no prior art that could come in way of the grant of his patent application. Praful who lives in the same housing society and had seen the testing of the invention in their society, came to know about the patent application when it was published in the Journal of the Patent Office and opposed the patent application on the ground that he had witnessed the use of the invention in a public place in India before the patent application was filed. Please draft the statement in reply that is required to be submitted to the Patent Office.
- 4. A ship named 'Voyager' registered in Panama and operated by 'White Waterlines' from Brunei accidentally entered the territorial waters of India in the Bay of Bengal. The Indian Coast Guard confiscated the ship and brought it to the Chennai Port. Upon inspection, it was found that Voyager had an 'Under Water Exploration Robot Arm' for its actual needs. The said equipment contains many features that are claimed in a patent granted to the Indian Maritime University (IMU). IMU files an infringement case against the owners of the vessel. White Waterlines approaches you for advice. Draft a note for your client suitably advising them in accordance with the provisions of the Patents Act, 1970?

Part B (60 Marks)

Part B1

For any one of the two specifications (1 and 2) stated below,

I. draft 5 claims

II. draft an abstract (maximum of 150 words) and

III. provide an appropriate title

 $1 \times 30 = 30 \text{ marks}$

Specification No. 1

The invention generally relates to a device for cutting or cracking open nuts or hard fruits of variable size. The invention particularly relates to a device for cutting open coconuts of various shapes and sizes for domestic use and use in temples and in small-scale industries.

Coconuts find extensive use in domestic and industrial applications in various forms such as coconut shavings, coconut water, coconut-milk, coconut oil, desiccated coconut, coir etc. Coconut is also used in foods, cosmetics, personal care products, neutraceuticals, etc. In many countries, coconuts falling from trees are wasted due to high costs involved in plucking and breaking coconuts. Breaking of coconuts is usually done manually. Holding a coconut in

one hand and using a heavy metallic object in the other hand to break the coconut tends to damage the nerves and muscles of the operator over a period of time.

A need therefore exists for a device that can be used in homes, temples, hotels, and restaurants. It should be simple, easy to operate and flexible enough to cater to different sizes and types of coconuts, with a capability of being automated.

Description:

As illustrated in Fig. 1, the coconut breaking device has a vertical stand (1) having grooves and notches (4), a coconut holder (2) having an adjustment knob (3) and a receptacle / container (5) placed over a base (6). The vertical stand (1) is connected to the base (6) at its one end and is connected to a rod, which has a fulcrum at the point where the said rod is connected to the vertical stand (1). This rod has a sharp edged laminar blade/knife (7) at its one end and a handle (8) at its other end. The base (6) can be mounted or attached rigidly to any flat surface for operation. The grooves and notches (4) on the vertical stand (1) allow appropriate vertical positioning of the coconut holder (2). The receptacle (5) is provided at the base (6) to collect coconut water. The prong like structure of the coconut holder (2) allows the coconut to be grasped firmly and thereby minimizes the risk of accidental slippage.

A coconut is held in between the prongs of the coconut holder (2). Vertical position of the coconut holder (2) is adjusted suitably. An operator moves the handle (8) in the upward direction causing the knife (7) to come into contact with the coconut, placed in the coconut holder (2) thereby slicing the coconut into two pieces. The motion can be as swift as the situation demands, i.e. depending on the outside crust of the coconut. The coconut water is collected in the receptacle (5). The handle (8) is made of a material that prevents injury to the hand of the operator e.g. leather, cloth etc.

In an embodiment of the invention, the process can be automated by using electrically operated parts. Any such embodiment will fall within the scope of this invention.

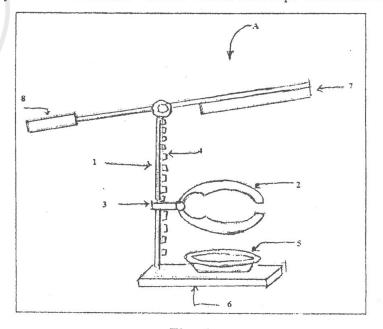


Fig. 1

Specification No. 2

The invention in general relates to substances for removing dirt from leather and/or for coloring the leather. In particular, the invention relates to a shoe polish.

The object of the invention is to provide a shoe polish which may be readily and easily applied to ordinary leather shoes to color them with any desired tint, or to match or harmonize them with the costume of the wearer. A further object of the invention is to provide a shoe polish as mentioned which may be readily removed from the shoes when it is desired to change the color thereof. A further object of the invention is to provide a shoe polish as mentioned which will not be deleterious to the leather but which on the contrary will serve to keep the leather soft and pliable. Other objects will appear hereinafter.

In carrying out the invention, preferably the shoe polish (or dressing) is applied to the leather in the seven positive colors namely: yellow, red, blue, green, brown, black, and white. The user can also compound the desired tints therefrom as needed, without departing from the scope of the invention.

Description:

The composition of the shoe polish is as follows:

Powdered coloring matter	4 parts by weight
Water, containing a small quantity of salt, sodium carbonate and an egg	8 parts by weight
Lard oil	1 part by weight
Syrup (corn or cane or mixture of both)	4 parts by weight
Mucilage formed of gum arabic and water	8 parts by weightage

4 parts by weight of powdered coloring matter is ground well into 8 parts of a first mixture of salt, sodium carbonate and a well-beaten raw egg in 1 litre of warm water to form a second mixture. About 60 grams of salt, 15 grams of sodium carbonate and 60 grams of beaten egg will usually be sufficient. The coloring matter is preferably chrome yellow, chrome red, ultramarine blue, chrome green, burnt umber, bone black, and zinc white. To twelve parts of the said second mixture thus formed is added 1 part of lard oil with stirring after which are added four parts of syrup and eight parts of mucilage. The syrup used is preferably ninety per cent corn syrup and ten per cent cane syrup, although either may be used separately or in different proportions; and the mucilage is formed by dissolving 500 grams of gum arabic in 2.5 litres of water resulting in the final composition, which is allowed to stand for one week after which it is ready for use. Egg is added to the water for the color and it also helps to keep the leather soft and adds luster to the polish. The salt preserves the leather and keeps it soft and pliable and also prevents the polish from cracking. The syrup and mucilage are added for an adhesive and to give luster to the polish.

In using the polish (or dressing) two or more of the colors may be mixed together to form a dressing of the desired tint. Usually two applications of the dressing will give an even color although sometimes three or more may be preferred. Unless the dressing has remained upon the leather for a great length of time it may be readily washed off to be replaced by another tint.

Part B2

A client meets you and provides technical information regarding his invention. Draft a complete specification, for <u>any one</u> of the following descriptions, for filing in the Indian Patent Office.

While preparing the complete specification, do not redraw the figures. However, you may refer to the figures in the specification as Fig. 1, Fig. 2 and Fig. 3.

 $1 \times 30 = 30 \text{ marks}$

Question 1

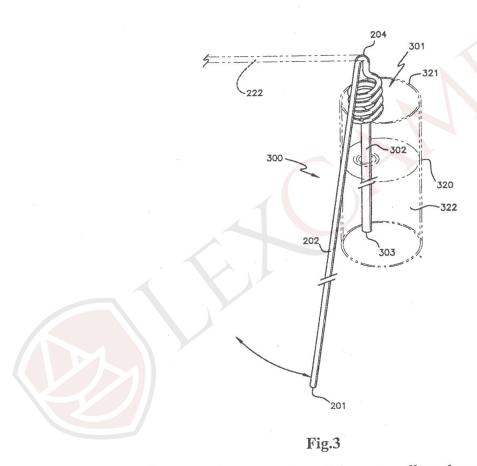
This invention is about a down-flow drinking straw that delivers liquid below the water level of a drinking vessel, while eliminating siphoning after an individual has stopped drinking, to reduce the amount of liquid spilled. The invention finds application in hospitals, convalescent homes and private homes for use by bed-ridden individuals.

We are familiar with the use of a straw that is used to sip liquid from a cup or a glass. A problem arrises when the delivery end of the straw is below the fluid level of the glass as a siphon is created due to which even after the person stops sucking the straw, fluid continues to flow out from the straw. This can be undesirable as liquid can spill on the person's face and clothes. There is a lot of prior art dealing with this problem but no straws with anti-siphoning features have been invented yet. Complicated straws with a variety of check valves to avoid back flows are however available. Straws with controlled pumping systems are also available. The present invention overcomes all the drawbacks of the known straws.

Figures 1 provides a schematic diagram of the construction of the straw of the present invention. Figure 2 provides a view of a patient using the straw in a hospital.

Note the straw having a straight supply tube portion connected by an adjustable bend to another straight pickup tube portion with an increased diameter portion below the adjustable bend. Also note the nature of the adjustable bend so that the supply tube portion is above the increased diameter portion when the straw is released. Once the supply tube portion is above the increased diameter portion of the tube, the increased diameter portion provides a volume of liquid to reverse the siphon and pulls the remaining liquid in the supply tube portion back into the glass. The volume of liquid in the enlarged diameter portion of the straw exceeds the volume of the entire supply tube portion.

Several variants of the straw are possible. Figure 3 illustrates one such variant.



A side view of a glass containing a variant of the anti-spilling down flow drinking straw, having a spiraling pickup tube

In the variant illustrated in figure 3, the straw has a long straight supply tube portion connected by an adjustable bend to another straight pickup tube portion, with an increased diameter portion in the supply tube portion that extends from below the adjustable bend downwardly. In this case, the spiral sections of straw connect the increased diameter portion to the adjustable end. The spiral sections are most useful when a container having a cover with a small opening is used (such as aluminium can). The straw is rotated and the lower spiral sections of the straw are routed through the opening and below the cover. This results in the spiral sections of the straw gripping the cover from below and above thus supporting

the straw on the container. By supporting the straw's pickup tube portion, the spring action of the adjustable bend is better able to lift the supply tube portion to the correct height for draining the straw. The spring action itself can be provided by the spiral sections. The increased diameter portion in this embodiment extends to the bottom of the pickup tube.

The actual material used to make the straw may be any of a number of available plastics, acrylics, polyurethanes, etc., as long as the material provides the spring function of the adjustable bend. Various colours and reservoir shapes may also be envisioned for aesthetic and entertainment purposes.

Question 2

Bilayer tableting technology has become popular in recent times. Bilayer tablets offer several advantages over conventional tablets.

The standard generic dosage forms of Analgesic-Antipyretic drugs have maximum effectiveness only for a few hours, e.g. 4 to 6 hours. Therefore, a patient needs to take such medication as least 2 to 3 times a day, which is undesirable.

It is desirable to offer patient friendly dosage forms that need to be taken only once day and yet ensuring uniform concentration of the drug in the serum for a 12 to 24-hour period. Patient compliance will be maximized when frequent dosing is avoided and relief is available for a longer period.

Formulating oral dosage form of Aceclofenac has remained a challenge in view of its poor or lack of solubility. Aceclofenac being insoluble in water, needs to be combined with solubilizers to improve the bioavailability. The disease conditions where Aceclofenac is used requires immediate relief and effectiveness on a continued uniform level for a prolonged period of time.

By "immediate release core", it is meant for purposes of the present invention that the tablet core containing the therapeutically active agent(s) meets the disintegration and/or dissolution requirements for immediate release tablets of the particular therapeutically active agent(s) included in the tablet core, as set forth in the USP XXII, 1990 (The United States Pharmacopeia).

By "sustained release", it is meant for purposes of the present invention that the release of the therapeutically active agent occurs such that blood levels are maintained within a desired therapeutic range over an extended period of time, e.g., at least about 8 and preferably from about 12 to about 24 hours. The "dissolution requirements" and "disintegration requirements" referred to above are conducted using the equipment and tests specified in the USP XXII and conducted pursuant to the individual Official Monographs of USP XXII for the particular therapeutically active agent(s) included in the tablet core.

Prior art discloses

- analgesic composition with uniform bioavailability over a prolonged period.
- sustainable oral dosage forms of aceclofenac.

The invention discloses oral dosage pharmaceutical composition of aceclofenac that provides uniform blood level concentrations over 12 hours to 24 hours a day. A bilayer oral dosage form of the water insoluble drug is formulated with a first layer which offers immediate release and a second layer which offers the drug from a sustained release matrix over 12 hours to 24 hours a day. The first layer for immediate release is formulated to release aceclofenac into the blood stream to initiate and achieve peak level concentrations as desired within 15 minutes.

The immediate release component is prepared by mixing 30% of total Aceclofenac in the composition with Betacyclodextrin along with pharmaceutically acceptable excipients. The sustained release component was prepared by mixing 70% of total Aceclofenac with pharmaceutically acceptable excipients selected from PVP, hydroxyl propyl methyl cellulose (HPMC), carboxy methyl cellulose (CMC), glyceryl monosterate poloxamer and surfactants, based on hydrogenated castor oil (PEG-60, PEG-40).

The Aceclofenac composition has following advantages:

- (a) Rapid availability in bloodstream and hence early onset of relief.
- (b) Uniform plasma level concentrations of aceclofenac over prolonged period.
- (c) Lower frequency of dosage and hence better patient compliances.

The bilayer tablet is prepared using the granules/pellets of immediate layer prepared by solvent/water based dissolution followed by dry granulation process and the sustained release granules/pellets prepared by the non-aqueous wet granulation process and compressing the two grades of granules/pellets using a C-300 or CTX II A Catmark Rotary Tablet Press. The bilayer tablet can be prepared either as a tablet in tablet form or as a conventional bilayer tablet using the above equipment.

The tablet prepared by compression is thereafter subjected to standard evaluation procedures such as disintegration, dissolution as well as bioavailability studies to determine that the desired blood level concentrations over a 12 hour or 24 hour sustained release period is met as preset in the objective of the formulation.

Examples

Aceclofenac in the present invention is incorporated in a total quantity of 100mg for standard SR dosage from and 200mg for Forte dosage form.

Immediate Release layer

30gms Aceclofenac is dissolved in 50ml solvent selected from acetone or ethyl alcohol or a combination thereof and mixed with Betacyclodextrin (50gms) dissolved in 30ml de-ionized water. The mixture is stirred to evaporation with moderate heating (40 to 50°C) to form a uniform paste comprising aceclofenac-betacyclodextrin complex. The complex so obtained is subjected to dry granulation by precompression followed by granulation or pelletisation and blended with lubricants.

Sustained Release layer

70gms of aceclofenac is dissolved in 50ml of acetone or ethyl alcohol or a combination thereof. 50gms of HPMC and 30gms of Povidone is added followed by 0.5gms of sodium lauryl sulfate along with 50 ml of deionized water.

The resultant solution was spray dried to produce a solid powder using a standard spray dryer. The solid powder is subjected to dry granulation by blending with lubricants by precompression or roll compaction followed by granulation/pelletisation.

The granules of the immediate release layer and the granules of the sustained release layer are directly fed into the tablet compression machine to obtain a standard bilayer tablet or a tablet in tablet dosage form. The tablet is subjected to standard tests such as disintegration, dissolution as well as compliance to the preset bioavailability parameters.

The immediate release layer composition is

Aceclofenac – 30% of the total aceclofenac in the composition

Betacyclodextrin – 5 to 10% of Aceclofenac in the immediate release layer.

Pharmaceutical excipients for granulation -2 to 3% of the Aceclofenac in the immediate release layer.

The sustained release layer composition is

Aceclofenac – 70% of the total aceclofenac in the composition

Hydroxy propyl methyl cellulose – 40 to 50% of Aceclofenac in the sustained release layer.

1-venyl 2-pyrrolidone -50 to 60% of the Aceclofenac in the sustained release layer.

Pharmaceutical excipients for granulation -5 to 10% of the total weight of the sustained release layer.