

Paper II – Practical

(Exploitation of Patents – Drafting, Specification & Patent Writing)

Time: 2 ½ hours.

TOTAL MARKS: 60

INSTRUCTIONS TO CANDIDATES

The questions to be interpreted as given and no clarification can be sought from the invigilator.

You are required to draft an US patent application with the following data and information. You are required to attempt either A or B (any one). Drawings are not needed and do not attach

A)

A study was conducted to evaluate the release of recombinant human growth hormone (rhGH) from a non-polymeric sucrose acetate isobutyrate sustained release system.

The system comprised sucrose acetate isobutyrate (SAIB) and a solvent. Two spray freeze dried formulations of rhGH were evaluated, rhGH in sodium bicarbonate and rhGH complexed with zinc. The rhGH powders were homogenized with various systems at two different protein loads (5 and 15% w/v). The release rate and protein stability was monitored by reverse phase-HPLC, size exclusion chromatography and BCA for 28 days. The effect of zinc and surface area on release rate and protein stability was also investigated.

The in vitro results for the zinc complexed rhGH indicated a very low burst from 0.1 (SAIB:Ethanol) to 2.2% (SAIB:Miglyol) followed by protein release over 28 days. The release rates and total protein released by the different preparations varied widely. The high protein load (15%) and the low protein load (5%) released approximately the same amount of protein indicating that the surface area of the sucrose acetate isobutyrate:solvent/protein mix proved to be an important factor in the initial burst and the release rate. In vitro experiments that increased the surface area of the sucrose acetate isobutyrate:solvent/protein in contact with the release medium resulted in increased bursts of 1 to 4% with a higher total percentage of released protein. The bicarbonate rhGH suspension had a higher initial burst (7 to 14%) and released more protein in 28 days when compared to the zinc complexed rhGH suspension.

Changing the solvent polarity, the ratio of solvent to SAIB, and the addition of zinc can modify the

release rate of the rhGH from sucrose acetate isobutyrate:solvent systems. These results demonstrate that the sucrose acetate isobutyrate: solvent delivery system is capable of providing sustained release of intact rhGH in vitro.

The growth hormone (GH) is preferably human growth hormone (hGH), preferably biologically active non-aggregated hGH. According to the present invention the GH is complexed with at least one type of multivalent metal cation, preferably having a valence of +2 or more, preferably from a metal cation component of the formulation.

Suitable multivalent metal cations include biocompatible and non-toxic metal cations. A preferred metal cation component for GH is Zn⁺². Typically, the molar ratio of metal cation component to GH is between 1:1 and 100:1, preferably, between 1:1 and 20:1 and preferably between 1:1 and 10:1.

EXPERIMENTS

Methods: Preparation of zinc complexed rhGH: A 20 mg/ml rhGH solution in 25 mM sodium bicarbonate was complexed with zinc at a rhGH:zinc ratio of 10:1. The rhGH/zinc suspension was spray freeze dried to create a fine powder that is approximately 70% rhGH by weight.

Preparation of bicarbonate rhGH: A solution of approximately 5 mg/ml rhGH in 10 mM ammonium bicarbonate was lyophilized to produce an excipient free powder.

SAIB/rhGH suspension preparation: The rhGH SABER suspensions were prepared by mixing rhGH powders with SABER formulations using a shear homogenizer. Release Rate Determination: 0.2 mL of each rhGH/SAIB suspension was added to eppendorf tubes in duplicate, then 0.5 mL of release medium (50 mM HEPES, 10 mM KCl, 0.1% NaN₃, pH 7.2) was added above the suspension. The eppendorf tubes were incubated at 37 deg. C. and sampled at various time points. At each time point, 0.5 mL of release medium was removed and 0.5 mL of fresh release medium added. Collected samples were stored at -70 deg. C. prior to analysis. The release samples were analyzed for protein concentration and protein quality.

BCA Assay: The BCA assay in a microtiter plate format was used to determine the protein concentration of the release samples. rhGH protein standards were prepared in release medium at 0, 0.005, 0.01, 0.02, 0.05, 0.2, 0.5 g/ml. 0.02 mL of each blank, standards, and release samples were mixed with 0.2 mL of the BCA working reagent in a microtiter plate. The microtiter plate was incubated at 37 deg. C. for 1 hr and the absorbance determined at 562 nm using a microtiter plate reader. The protein concentrations of the release samples were determined from the standard curve using a four parameter non-linear curve fit. The amount of oxidized variants in the rhGH release samples was determined by RP-HPLC. This assay was run using a 4.6.times.15 cm, 8 mm, 300 angstrom PLRPS column held at room temperature. The mobile phase A contained 50 mM NaH₂PO₄, pH 7.0 and mobile phase B contained 20% propanol in acetonitrile. The separation was isocratic at 49% (B) and the eluent was monitored for absorbance at 214 nm.

Size Exclusion Chromatography was used to determine amount of monomer present in the release samples. This assay was run using a 7.8.times.300 mm TSK 2000SWXL column held at room temperature. The mobile phase used was 50 mM NaH₂PO₄, 150 mM NaCl pH 7.2 with a flow rate of 1.0 ml/min and a run time of 20 min. 10 g protein was injected and the eluent monitored for absorbance at 214 nm.

In vivo pharmacokinetics of rhGH were determined in after SC injection of rhGH SABER formulations (SAIB:Benzy alcohol; 85:15 w/w and SAIB:Benzy benzoate; 70:30 w/w) in Sprague Dawley (SD) rats. Serum rhGH levels were determined by ELISA (Genentech) with an assay detection limit of 0.1 ng/mL.

Results and Discussion:

Solvent Ratio - The effect of the SAIB/solvent ratio on protein released was examined by plotting the cumulative release for rhGH in SAIB:ethanol ratios, 85:15, 75:25, and 50:50 (w/w). This plot is shown in FIG. 2A. The 85:15, 75:25, and 50:50 w/w ratio resulted in a 10%, 13%, and 26% release of the protein at 28 days. The SAIB/solvent ratio is a factor in release rate, but it does not effect the initial burst for the SAIB:ethanol formulations.

SABER Solvent Type - The effect of solvent on the rate of release from SABER is shown in FIG. 3. All SAIB/solvent preparations show a low initial burst of rhGH in the first day and protein release out to 28 days. The rhGH/SAIB:miglyol suspension was the only sample with a poor release curve. The total amount of protein released over the 28 days for all samples was no higher than 13% of the total protein load. This result was expected due to the lack of enzymatic degradation in these in vitro experiments.

Loading - The release results for all SAIB/solvent preparations and both protein loads are detailed in FIGS. 2B C. Ideally a one month sustained release system should have an initial burst of approximately <10% and an average daily release of 3%. The results for the SABER with rhGH show a burst from 0.1 to 2.2%, with an average daily release over 28 days from 0.1 to 0.9%. These values are extremely low but expected due to the lack of in vitro degradation of SABER.

Formulation - The effect of zinc on rhGH release from SABER was evaluated by comparing release rates of zinc complexed rhGH and lyophilized rhGH in bicarbonate from SABER. 5% w/v suspensions were prepared using two SAIB/solvent preparations, benzy benzoate, and ethanol. The release curves are shown in FIG. 4. The bicarbonate rhGH produces a higher initial burst than the zinc complexed rhGH for both SABER preparations. The initial burst for the bicarbonate rhGH from SAIB:ethanol is 6.53% compared to 0.53% for the zinc complexed rhGH. The initial burst from SAIB:benzy benzoate is 14.64% for the bicarbonate rhGH compared to 1.06% for the zinc complexed rhGH. The daily release and the overall total protein released is also much higher for the bicarbonate rhGH. These results indicate that excipients such as zinc can affect protein release from SABER. This effect may be due to differences in particle morphology or more likely differences in protein solubility. Zinc complexed rhGH has lower solubility than the bicarbonate formulation. The integrity of the released protein was determined by RP-HPLC and SEC. The results indicate a decrease in native protein over time (FIG. 5). This decrease was most pronounced in protein released from SABER formulations containing benzy benzoate and ethanol. Protein released from the 5% load formulations was less native than protein released from the 15% load formulations. This may be due to a decrease in the protein:solvent ratio in the 5% load formulations, leading to higher solvent exposure in the release medium. During the course of these experiments several grades of benzy benzoate were used (reagent grade and USP grade). Samples from experiments using these solvent grades were tested for oxidation (RP-HPLC) and aggregation (SEC). The results show protein released from the SABER formulations containing USP grade benzy benzoate were less degraded than protein released from reagent grade benzy benzoate (FIG. 6) After 21 days the amount of rhGH monomer remaining was over 90% for the USP grade benzy benzoate formulation compared to 75% for the reagent grade formulation. The reversed phase results also show an improvement in protein quality with the USP grade benzy benzoate. At 21 days 80% of the main peak remained compared to 60%

seen with the reagent grade solvent. The purity of solvent used in SABER formulations has a direct effect on protein quality and thus should be monitored.

To determine the effect zinc had on the protein release rate, zinc complexed GH and bicarbonate rhGH were mixed with two SABER formulations containing ethanol and benzyl benzoate as solvents. In vitro release experiments were carried out using an EDTA containing release medium (50 mM HEPES, 10 mM KCl, 50 mM EDTA, 0.1% NaN₃, pH 7.2). These results are summarized in FIG. 7. The presence of EDTA in the release medium increased both the initial burst and the overall release for both rhGH SABER formulations.

Surface Area - Exposed solvent accessible surface area and SABER:buffer ratio appeared to influence release of rhGH from SABER formulations (FIG. 8). When a larger surface area and lower SABER:buffer ratio (>buffer volume) was used more rhGH was released. This result indicates that both exposed surface area and SABER:buffer ratio should be controlled during in vitro experiments.

Pharmacokinetics - In vivo pharmacokinetics show SABER formulations are able to deliver rhGH for prolonged periods of time with a fairly low initial burst (FIG. 9). However, SABER solvent properties play a large role in the release mechanism. The SABER formulation containing benzyl benzoate released >80% of available loaded material in the first 48 hrs while the benzyl alcohol formulation delivered target (10 ng/mL) levels of rhGH for the duration of these studies. When compared to control microspheres the benzyl alcohol formulation had a significantly lower initial burst yet maintained similar serum levels for 7 days.

Conclusions - In vitro release kinetics are dependent on SAIB/Solvent type, SAIB/Solvent ratio, excipients, release medium, and surface area.

The quality of the released protein is dependent upon the type of solvent and purity of solvent used in the SABER preparation. The rhGH SABER formulations can provide a low burst, sustained release system for delivery of rhGH. However in vivo kinetics could depend on protein formulation and SABER solvent choice.

Sustained release delivery systems are of interest because they can improve patient compliance, tolerability, product performance, and expand the market potential for a product. The SABER system is a novel injectable liquid non-polymeric drug delivery system (Smith and Tipton (1996) Pharmaceutical Research 13(3):300). The SABER system, which stands for Sucrose Acetate isoButyrate Extended Release, is composed of sucrose acetate isobutyrate (SAIB) and a plasticizing solvent. SABER is injected as a low viscosity liquid that increases rapidly in viscosity after injection. The resulting high viscosity matrix is adhesive, biodegradable and biocompatible.

FIG. 1: The structure of sucrose acetate isobutyrate is shown in FIG. 1.

FIG. 2: The effect of solvent ratio (FIG. 2A) and loading (FIGS. 2B and 2C) on the release of hGH from sucrose acetate isobutyrate formulations containing ethanol.

FIG. 3: The effect of solvent on the release of rhGH from sucrose acetate isobutyrate formulations.

FIG. 4: The effect protein formulation has on the relapse of rhGH from sucrose acetate isobutyrate formulations.

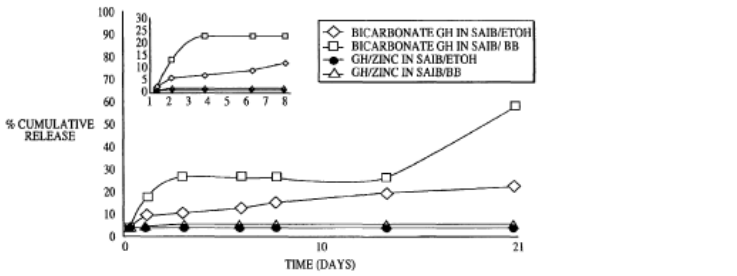
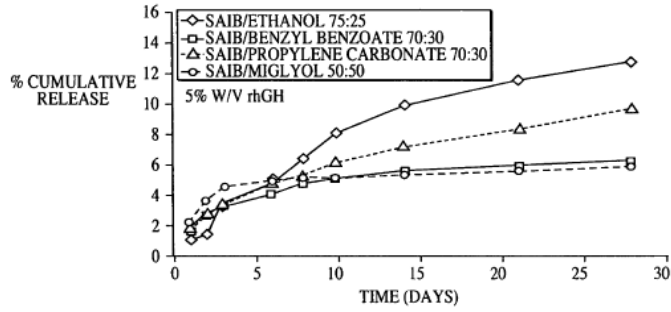
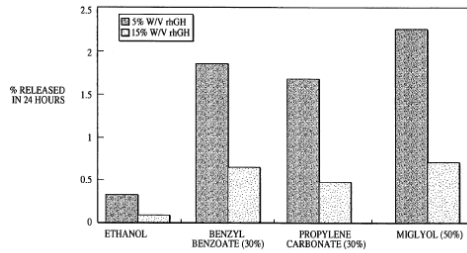
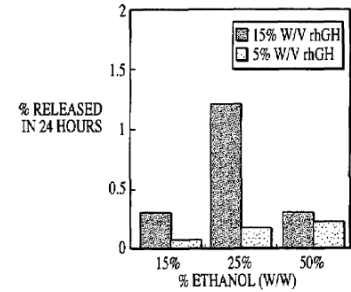
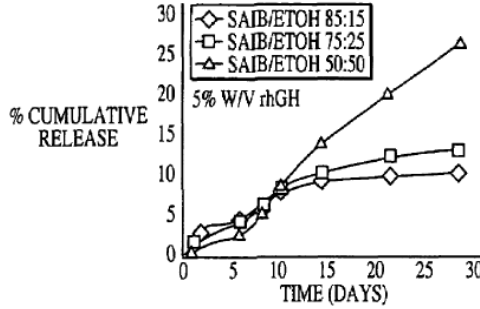
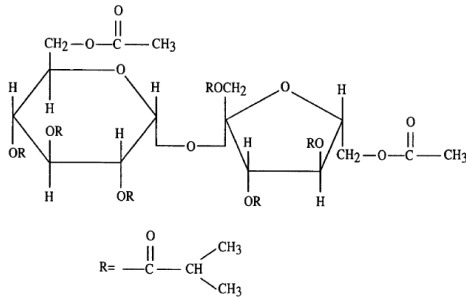
FIG. 5: Protein integrity after relapse from sucrose acetate isobutyrate formulations determined by native size exclusion chromatography and reverse phase HPLC.

FIG. 6: Effect of solvent quality on stability of rhGH released from sucrose acetate isobutyrate formulations containing reagent and USP grade benzyl benzoate.

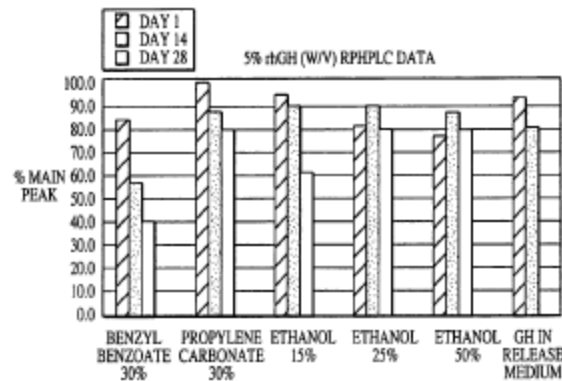
FIG. 7: The effect a chelating agent (EDTA) has on the relapse of zinc complexed rhGH from sucrose acetate isobutyrate formulations.

FIG. 8: The effect buffer exposed surface area and sucrose acetate isobutyrate buffer ratio have on the relapse of rhGH from sucrose acetate isobutyrate formulations.

FIG. 9: rhGH serum levels after subcutaneous administration of rhGH sucrose acetate formulation (SD rats 6/group, 15 mg/Kg).



SAIB-SOLVENT	GROWTH HORMONE FORMULATION	% RELEASE OVER 24 HOURS	% DAILY RELEASE 0-21 DAYS
ETHANOL (85:15)	ZINC	0.53	0.10
ETHANOL (85:15)	BICARBONATE	6.53	0.73
BENZYL BENZOATE (70:30)	ZINC	1.06	0.12
BENZYL BENZOATE (70:30)	BICARBONATE	14.64	2.16



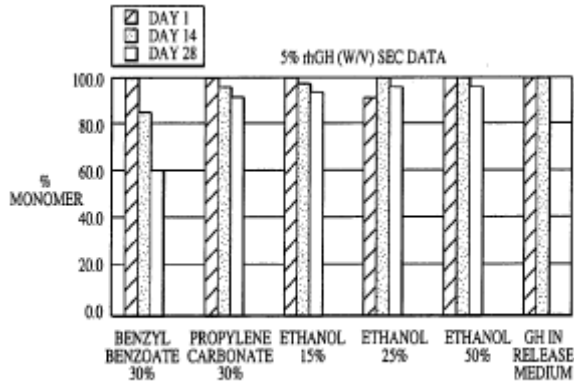


FIG. 5 B

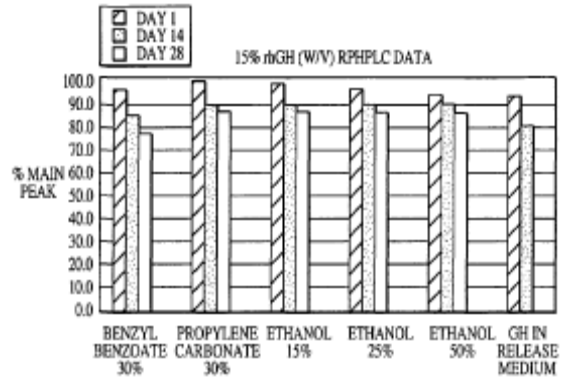


FIG. 5 C

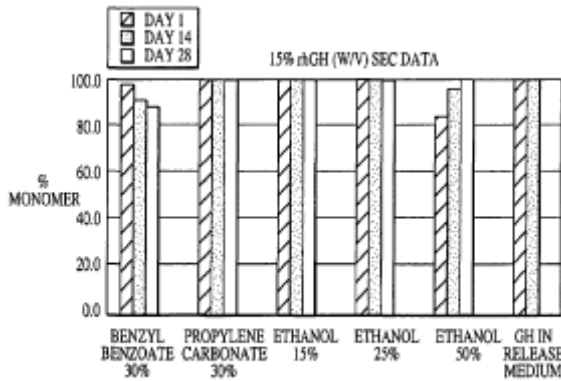


FIG. 5 D

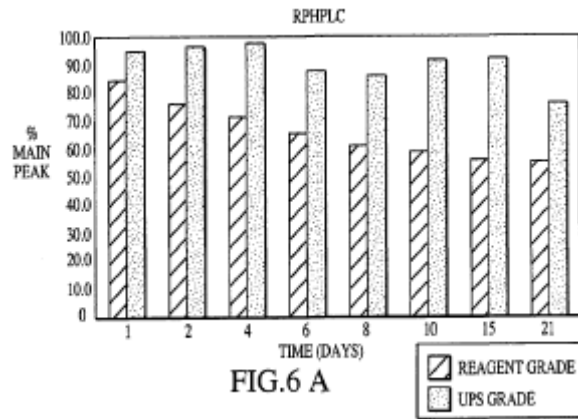


FIG. 6 A

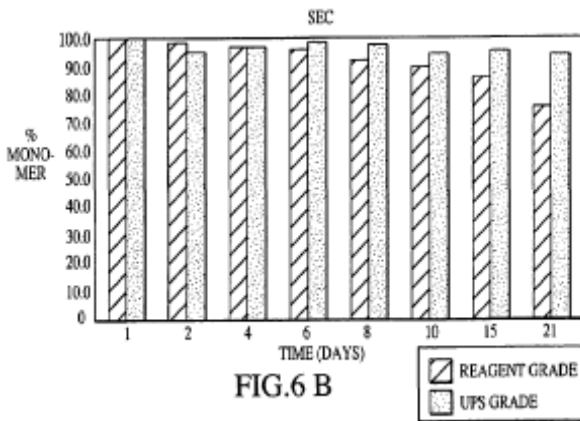


FIG. 6 B

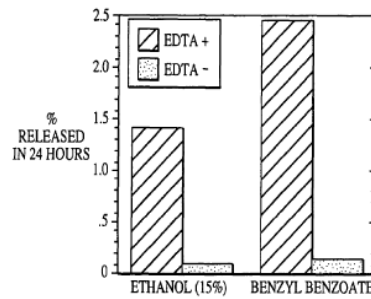


FIG. 7

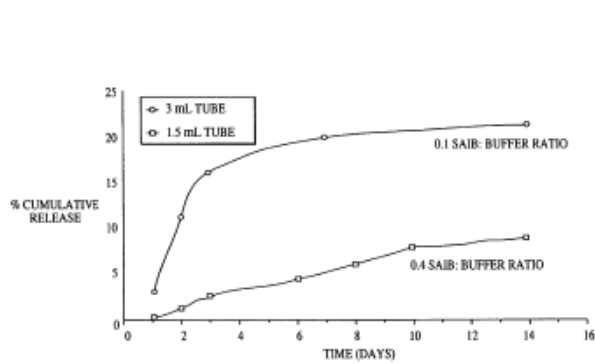


FIG. 8

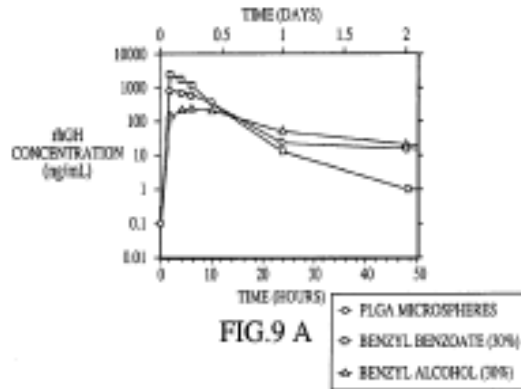


FIG. 9 A

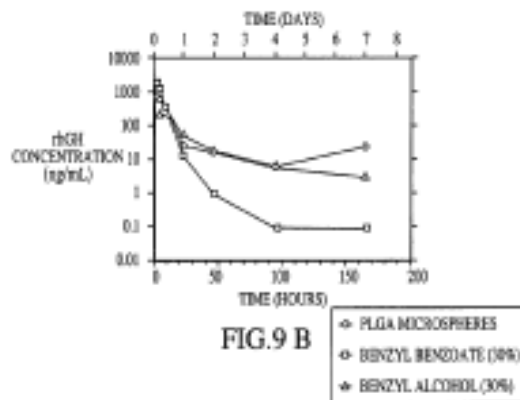


FIG. 9 B

Clinically, rhGH is administered daily in growth hormone deficient (GHD) patients. To decrease the dosing frequency and increase patient compliance several sustained release formulations are under development. Recently the FDA approved the first rhGH sustained release formulation. This formulation allows patients to decrease their dosing interval from daily to once or twice per month depending on rhGH requirements. However, the approved Depot formulation releases 10-20% of the encapsulated protein in the first two days leading to high rhGH serum levels.

B)

The present invention generally relates to portable air filtration and purification apparatus and is more particularly directed to a portable hat system which is suitable for gathering smoke exhaled upward by a smoker, removing odor and smoke particles from the air and returning the filtered and purified air to the surrounds of a user, thereby eliminating any objection to the smoking of cigarettes and the like by non-smokers in the area.

While the smoking of tobacco products, such as cigarettes, has been very popular over the years, a growing number of non-smokers find the aroma from cigarette smoke, and the associated smoke and ash product as a result of smoking quite objectionable.

This growing concern has prompted many governmental regulations as well as private company rules concerning appropriate times and places for smoking. This is unfortunate for the typical smoker because it has severely limited their use of tobacco products, and in many cases, has detrimentally affected their work habits, efficiency and potential for advancement and/or potential for new employment.

Unfortunately, for cigarette smokers, most occupations require interaction with a multitude of people, either individually or in conference. It is at these very times that a smoker still desires his or her cigarette, and it was not long ago that it was most socially acceptable to permit this.

Moreover, mass transit systems, such as commercial airlines, and social gatherings in theaters, restaurants, pubs, and the like, are other areas where a conflict between smoker and non-smokers wishes occur.

Because of the evolving social changes in our society, there is a need for a device to put the smoker and the non-smoker on equal footing. The present invention fills that need. A portable hat system is provided herein to enable the smoking of tobacco type products without disturbing or threatening nearby non-smokers.

A portable hat system for enabling the smoking of tobacco type products without affecting the environment, in accordance with the present invention, generally includes hat means for covering the head of a smoker, means for intaking ambient air into the hat means, means for removing combustion products released by the smoker, and means for exhausting the filtered air from the hat means. The intake ambient air flows in front of the smoker's face when the operating hat means is worn by the smoker, thereby gathering all the smoke products and delivering them to the means for removing combustion products.

More particularly, the portable hat system, according to the present invention, includes a lens/visor which is dependingly attached to the hat means and surrounding the face of the smoker when the hat means is worn by the smoker. In this manner, the visor provides a means of establishing an intake ambient air channel over the face of the smoker when the hat means is worn thereby. In addition, staging means may be provided for supporting a lit cigarette under the hat means in a position enabling the intake ambient air to flow therepast. Also, receptacle means may be provided and disposed under the hat means for receiving solid combustion wastes. The receptacle means is disposed in a position enabling the intake ambient air to flow therepast similar to the staging means hereinabove recited. Hence, the portable hat system provides a controlled environment which at all times captures and retains substantially all cigarette wastes.

It should be appreciated that since the staging means and the receptacle means are an integral part of the portable hat system, the present invention enables the user/smoker full opportunity to use his or her arms and hands during smoking without continuous lip contact with the cigarette. That is, the cigarette may be supported by the staging means, and ashed or extinguished in the receptacle, both of which are in the controlled environment of the portable hat system.

For use in construction areas, or the like, the hat means may also include hard hat means, such as reinforced plastic, or the like, for preventing injury to the smoker's head from falling objects when the hat means is worn by the smoker.

Specifically, the means for intaking ambient air may include a battery operated fan and rechargeable battery and the means for removing combustion products from the intake ambient air may include an electrostatic cathode screens, a removable filter/deodorizer cartridge and duct means for directing intake ambient air with combustion products through electrostatic cathode screens and through removable filter cartridge.

In order to provide comfort and ease of use of the present invention, the fan and the battery may be disposed in opposite ends of the hat means in order to balance the weight of the portable hat system, thereby causing the center of gravity thereof to be near the center of the smoker's head when the hat means is worn by the smoker. Hence, there is no inherent imbalance of the hat on the smoker.

As protection against the undesirable intake of fly ash or lit embers into the filtered cartridge, the means for intaking ambient air may also include cinder guard screen means for preventing the solid combustion products of a predetermined size from entering both the fan and the removable filtered cartridge.

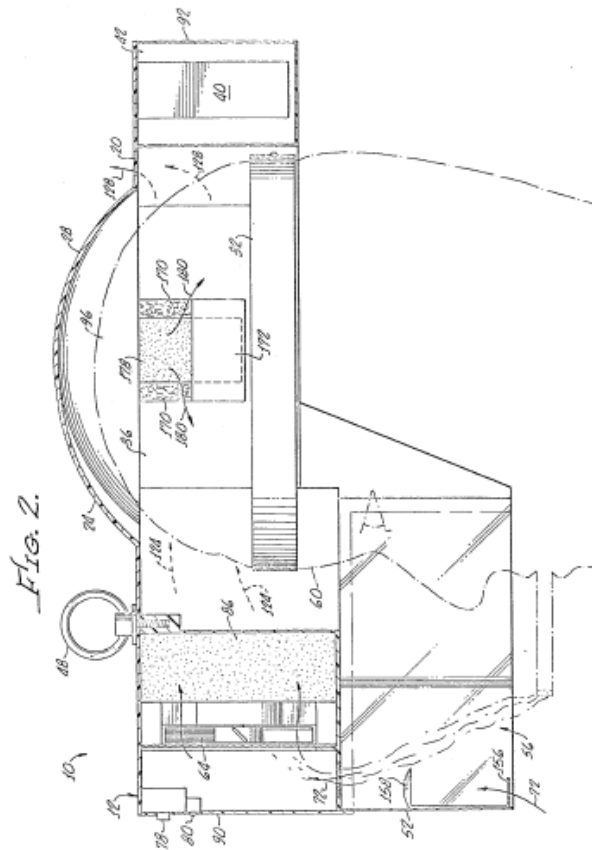
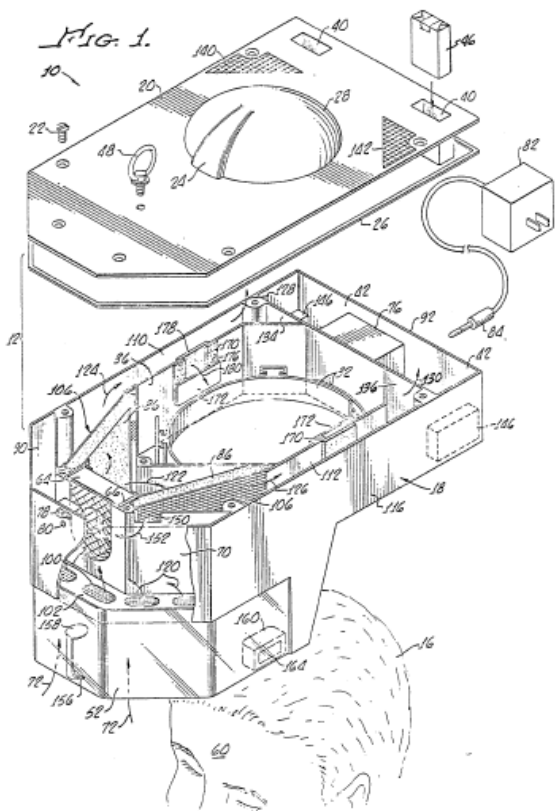
To provide efficient removal of combustion products, an electrostatic cathode screen may be provided along with a removable filter/deodorizer cartridge. Duct means provide for directing intake ambient air and combustion products past the electrostatic cathode means and through the removable filter/deodorizer cartridge. It should be apparent that the removable cartridge enables the efficiency of the combustion product removal means to be maintained indefinitely.

Importantly, the means for removing combustion products from the intake air may also include recirculation duct means for enabling at least a portion of the intake ambient air to pass through the removable filter/deodorizer cartridge more than once. This provides for partial recycling of filtered, or purified, air which also acts to increase a differential pressure across the filters for greater filter life and to further polish the discharge air between puffs of incoming smoke.

In situations where under hat humidity and/or temperatures are elevated, the portable hat system, according to the present invention, also may include a cooling duct means for enabling an adjustable amount of filtered and purified air to pass over the head of the smoker when the hat means is worn. For the convenience of the smoker, the hat means may also include pocket means for supporting at least one package of cigarettes and/or other smokers' materials for ready access thereto. In addition, to further please nearby non-smokers, scent means may be provided for adding a preferred scent to the purified exhaust filtered air.

The advantages and features of the present invention will appear from the following description when considered in conjunction with the accompanying drawings in which:

FIG. 1 is an exploded perspective view of the present invention; and FIG. 2 is a cross-section side view showing an intake ambient air channel over the face of a smoker/user.



Turning now to FIGS. 1 and 2, there is shown a portable hat system 10, in accordance with the present invention, which generally includes a smoker's hat 12. Specifically, the hat 12 may include a housing 18 and a lid 20 which may be assembled in a conventional manner by screws 22, or the like, with a pliable seal 26 there between to form an airtight seal there between.

The housing 18 and the lid 20 may be molded from any suitable material, such as plastic, and further, the lid 20 may be reinforced in any suitable manner, such as with a rib 24, to provide hard hat means for preventing injury to the smoker's head from falling objects (not shown) when the hat means is worn by the smoker.

A domed portion 28 may be molded into the lid to accommodate the protection of the smoker's head.

Individualized comfort and ease of wear is enabled by an adjustable harness 32 which may be removably attached to an interior wall 36 of the housing 18 in a conventional manner, the harness being of well-known conventional type, such as those used in helmets and the like, and adjustable for accommodating various head sizes.

Openings 40 in the lid 20 along with compartments 42 formed in the housing 18 provide pocket means for supporting at least one package of cigarettes 46 for ready access thereto and/or other smoking materials.

Optionally, a ring 48 may be attached to the lid 20 in order to hang the portable hat system 10 in a convenient storage location when not in use and/or while recharging the battery.

A perimeter lens 52, which may be removably attached to the housing 18 in any conventional manner, provides visor means for establishing an intake ambient air channel 56 over the face 60 of the smoker 16. (See FIG. 2).

It should be appreciated that the perimeter lens may be made of any suitable clear material to enable visibility therethrough or, it may be tinted. In fact, a plurality of perimeter lenses may be provided with different degrees of tint, with the selection of the lens used being made in accordance with the user's preference.

A battery driven fan 64 may be cushioned 66 mounted to an interior partition 70 of the housing 18 which provides means for intaking ambient air into the hat 12, with the ambient air flowing in front of the smoker's face 16, as shown by the arrow 72. In this manner, exhaled smoke is drawn upwardly and through the fan 64. The fan 64 may be of any suitable type and the cushions 64 ensure silent and vibration absorbing operation thereof. Power for the fan is provided by an optionally rechargeable battery pack 76 interconnected with the fan 64 by on/off switch 78, which may also incorporate a charging light 80 for indicating when the rechargeable battery pack 76 is being recharged by a DC power supply 82, which may be interconnected with the battery pack 76 by a common type connector 84, as well known in the art.

The sizing of the fan 64 and the battery pack 76 will, of course, vary upon the intended duty cycle of the portable hat system and may be easily determined by one skilled in the art. Importantly, however, since the fan 64, along with filter/deodorizer packs 86, hereinafter described in greater detail, and battery pack 76 comprise the heaviest elements of the portable hat system 10, the fan 64 and the filter packs 86 are disposed near one end, such as the front 90, of the portable hat system, while the battery pack 76 is disposed near the rear 92 of the portable hat system. This positioning balances the weight of the portable hat system 10 and thereby cause the center of gravity thereof to be near the center 96 of the smoker's head when the hat 12 is worn by the smoker 16.

Because there may be a remote possibility of flyash entering the fan 64 and filter packs 86, a cinder guard 100 may be integrally disposed in a horizontal partition 102 to provide means for preventing large and burning combustion products of a predetermined size from entering the fan and the removable filter cartridge 86. The cinder guard screen may be of any suitable small gauge and is

preferably formed from a metal in order to rapidly cool any impinging hot flyash or still burning particles of tobacco. This safety feature minimizes the possibility of unwanted combustion occurring in the filter packs 86 due to hot or ignited flyash.

In addition to the filter packs 86, electrostatic screens 106 contained between an outer wall 116 of the housing and inner wall 36 provide means for neutralizing residual combustion products, such as positively charged smoke particles in the intake ambient air.

The filter packs, or cartridges, may be of any suitable type well known in the art for removal of particulate cigarette combustion products and may include a layer of activated charcoal to deodorize the products of combustion. The electrostatic screens 106, which are interconnected to the cathode (not shown) terminal of the battery pack 76 also provide a well known method for converting positively charged ions in the exhaled smoke, into non-aggressive, non-clinging negative ions.

In operation, ambient air is drawn in front of the face 60 of the smoker 16 in the direction of the arrow 72 passes through the cinder guards 100 and enters the fan 64 as indicated by the arrows 120. Thereafter, the air is forced by the fan 64 into the filter packs 86 as shown by the arrow 122 where particulate matter is removed by filter packs 86, deodorized by activated charcoal and deionized by the electrostatic screens 106.

Thereafter, the filtered and purified air passes through ducts 110, 112, shown by the arrows 124, 126 and is ultimately exhausted upwardly, shown by arrows 128, 130 by inner back panels 134, 136 and through exhaust screens 140, 142. Thus, it is apparent that the back panels 134, 136, in combination with the exhaust screens 140, 142 provide means for exhausting filtered air from the hat means in an upward direction when the hat 12 is worn by the smoker 16. As a result, the filtered and purified air which has been also deionized by the cathodically charged screen 106 is returned to the ambient air in a manner such that nearby persons, even those in back of the smoker, are not disturbed by the movement or quality of the exhaust air. Optionally, scent packs 146 may be provided to add any preselected scent to the filtered and purified air as may be desired by the user thereof. The scent packs may be of any suitable type well known in the potpourri art and disposed in the flow of filtered air indicated by the arrows 128, 130, or adjacent thereto as shown in FIGS. 1 and 2, depending upon the amount of added scent desired.

As an additional feature, air recycle ports 150 may be provided in the interior partition 70 which provides recirculation means for enabling at least a portion of the intake ambient air to pass through the removable filtered cartridge units 86 more than once. As shown in FIG. 1, during operation, a portion of the air passing through the filters 86 is drawn by the fan 64 through the recirculation port 150, shown by the arrow 152. This partial recycling of purified air has the advantage in increasing the differential pressure across the filters for greater filter life and further polishing discharged air between exhaled puffs of air by the smoker.

In order to provide a total smoking environment for the cigarette smoker, a cigarette or cigar clip 156 provides means for supporting a lit cigarette or cigar under the hat 12. The clip may include a heat shield 158 and is removably attached to the lens/visor 52 in a conventional manner, such as by

Velcro or the like. Thus, staging means are provided for supporting a lit cigar or cigarette within the air channel 156, in order that smoke rising therefrom is carried into the hat 12 by the fan 64. Additionally, a cup 160 provides receptacle means which is removably attached to the lens/visor 52 by Velcro 164, or the like, for receiving solid smoking products, i.e., ashes and butts.

It should be appreciated that several Velcro pads 164 may be disposed within the lens/visor example, on the right and left hand sides, for accommodating the personal habits of the smoker.

Hence, it is obvious that the cigarette smoke, ashes and butts therefrom may be totally captured within the environment provided by the portable hat system 10. Not only can a person smoke any cigar or cigarette, but can hold or stage these within the intake ambient air channel 56 and dispose of ashes and butts in the removable cup 160, which is also within the intake ambient air channel 56.

Under warm conditions, cooling of the smoker's head 16 is provided by adjustable ports or tabs 170, 172 in the inner wall 36 which may be opened or removed in order to provide cooling duct means for enabling apreselected amount of filtered air to pass over the smoker's head 16. The tabs or ports may be held in either an open or closed position by Velcro 176 and, further, the size of the opening maybe adjusted by the amount of tab or port openings. As shown in FIG. 1, opening of the tab 172 enables air flow in the direction of arrow 180 to flow over and cool the smoker's head 16. As an additional feature, activated charcoal pads 178 may be provided to further filter and/or deodorize the air passing over the head of the user/smoker.

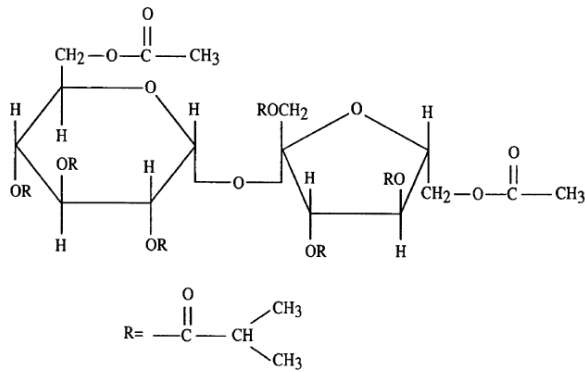


FIG. 1

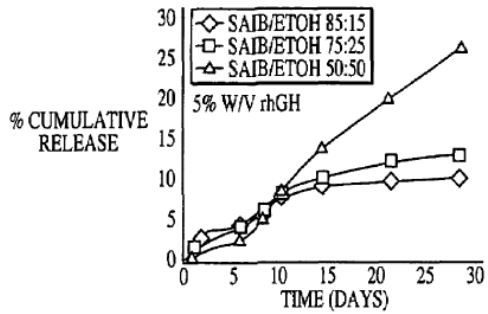


FIG. 2 A

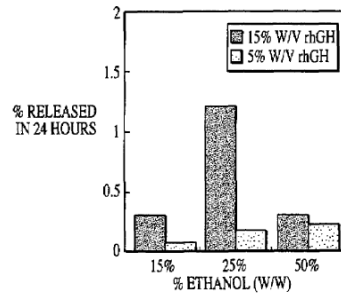


FIG. 2 B

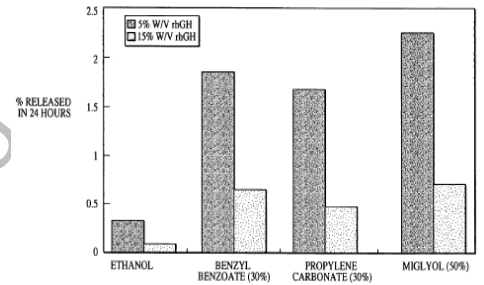


FIG. 2 C

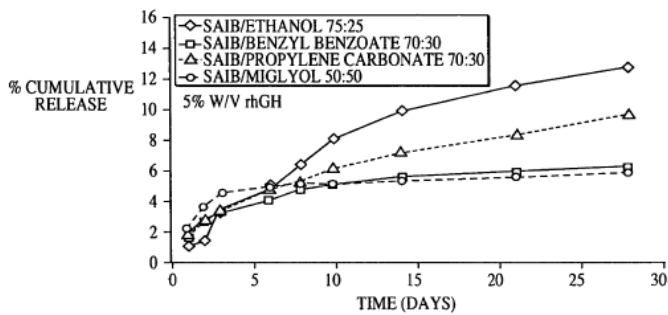


FIG. 3

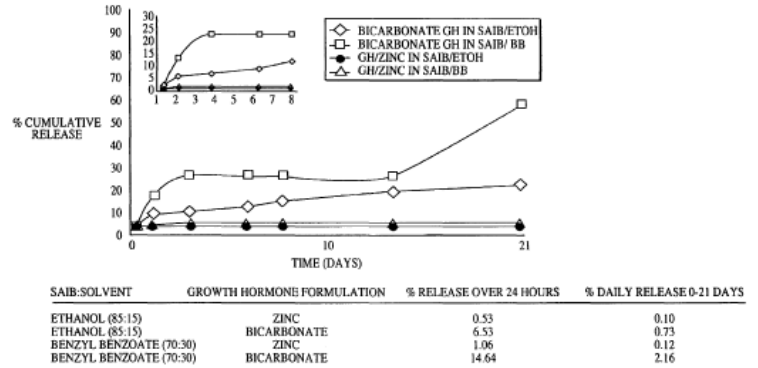


FIG. 4

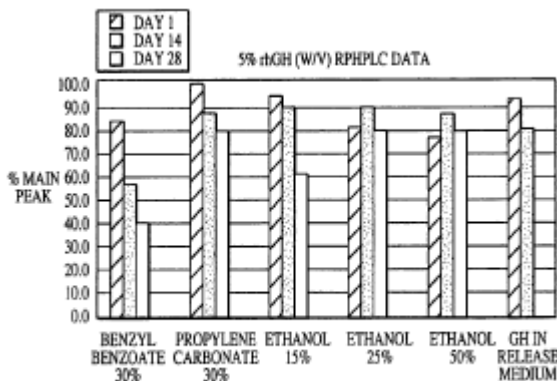


FIG. 5 A

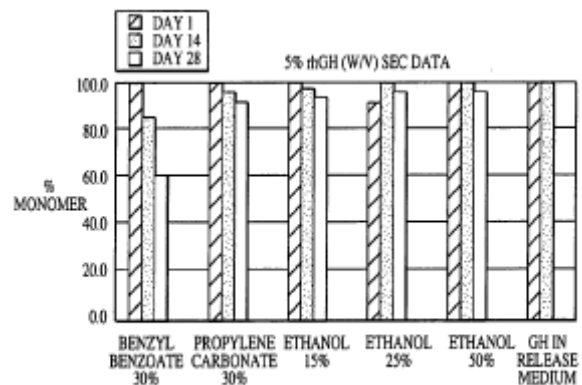


FIG. 5 B

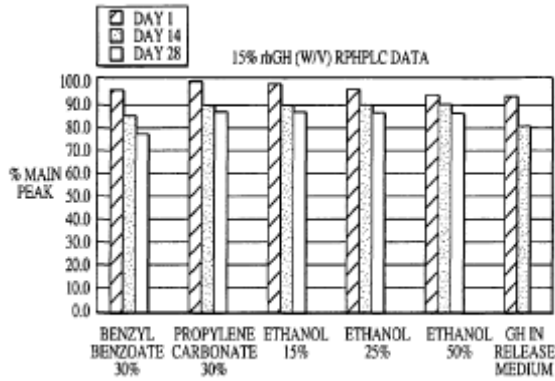


FIG.5 C

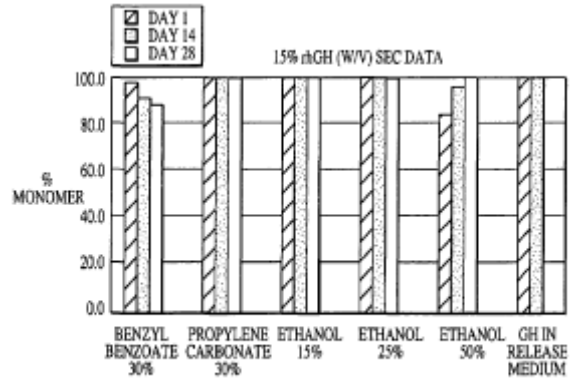


FIG.5 D

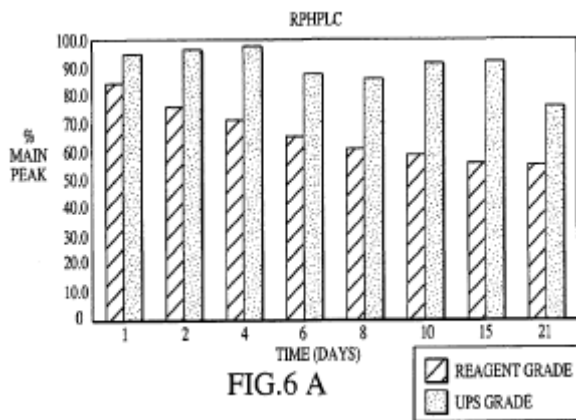


FIG.6 A

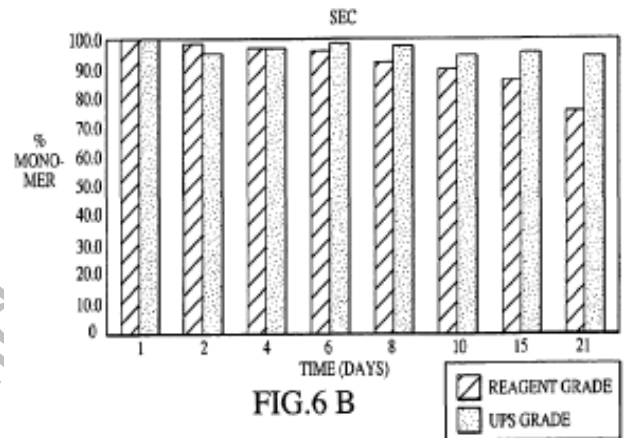


FIG.6 B

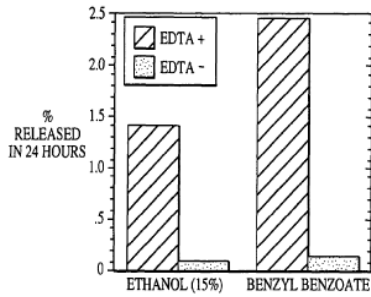


FIG. 7

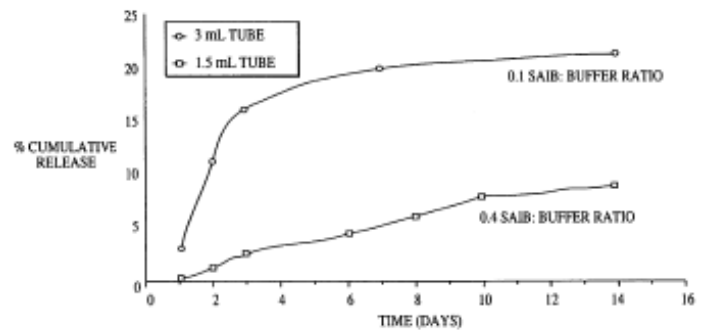


FIG. 8

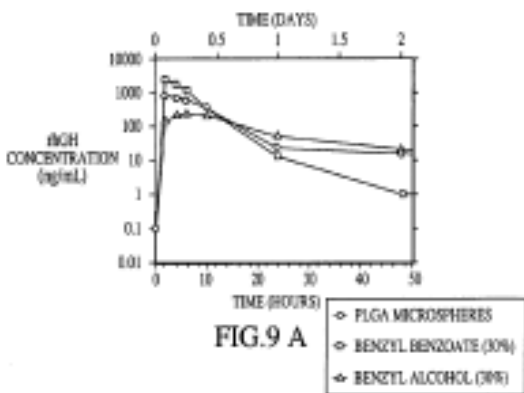


FIG.9 A

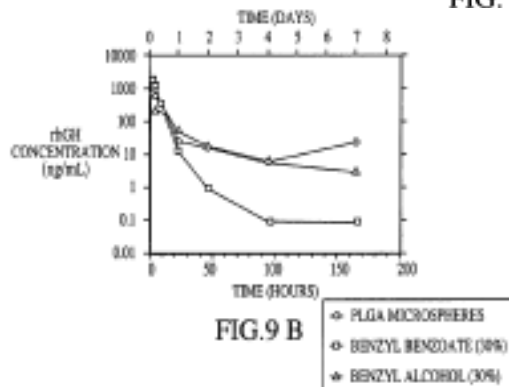
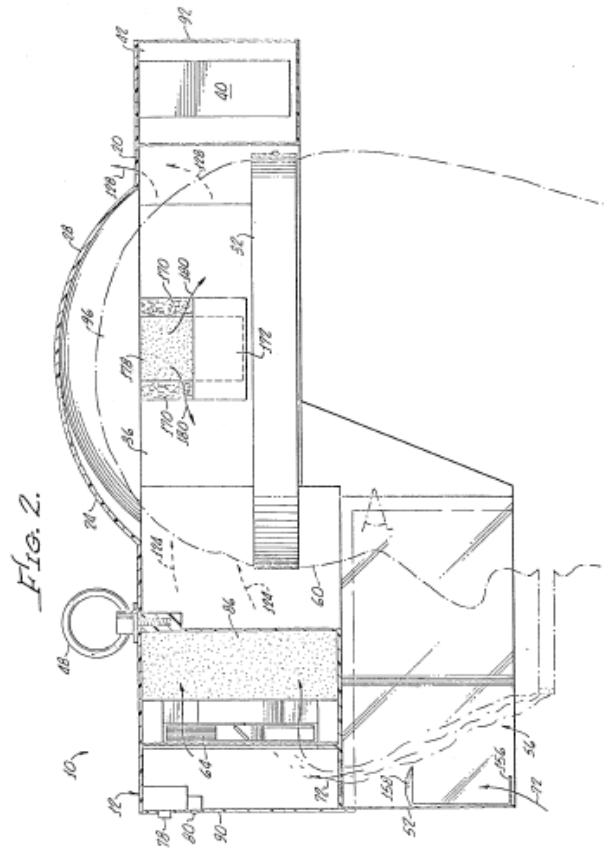
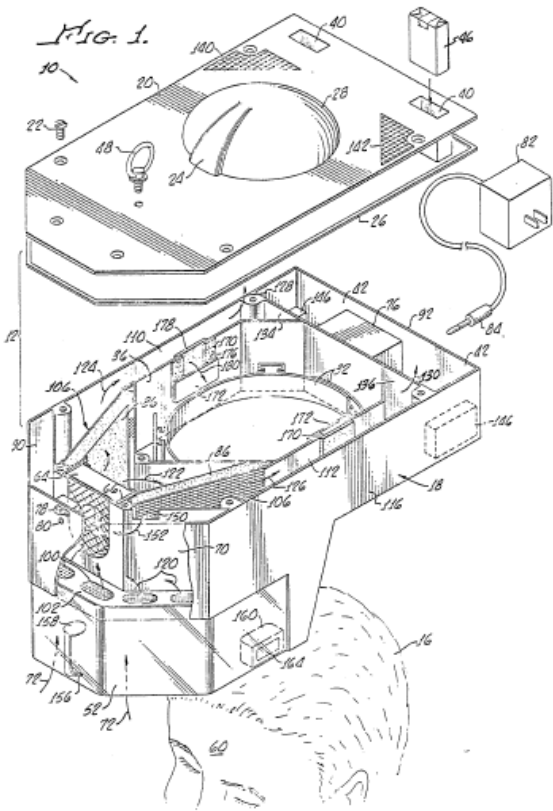


FIG.9 B



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