

## Summary of the Disclosure

In a first aspect the present invention provides a dry powder inhaler comprising:

- a mouthpiece for patient inhalation;
- a cover movable about a hinge to open and close the mouthpiece;
- a delivery passageway for directing an inhalation induced air flow through the mouthpiece;
- a channel extending from the delivery passageway;
- a reservoir for containing medicament, the reservoir having a dispensing port connected to the channel;
- a cup received in the channel and movable between the dispensing port and the delivery passageway, wherein the cup comprises a cup cam follower;
- a cup spring biasing the cup towards the delivery passageway;
- a yoke movable between at least a first position and a second position and including a yoke cam;
- whereby closing the cover moves the yoke between the first position and the second position such that yoke cam engages the cup cam follower and urges the cup against the cup spring to the dispensing port;
- and wherein the yoke cam, the cam follower, or both, is lubricated.

In a second aspect the invention provides a dry powder inhaler comprising a moving component which is:

- made from a plastics material which includes a slip additive; or
- at least partially coated with an oil, soap or stearic acid.

The inventors have surprisingly found that the dislocation of the cover results from an increase in friction between two moving parts within the inhaler: particularly the yoke cam and the cup cam follower. The increased friction is caused by excess dry powder coating and interfering with the interaction between the components. The increased friction results in an abnormally large reset force being required to slide the cup cam follower along the yoke cam, and therefore to close the cover of the DPI. The force can be increased to the extent that the hinges of the cover become dislocated and the cup cam follower does not return the dispensing port to receive a further dose of medicament. Although the applicant does not wish to be bound by theory, it is thought that the dislocation could occur owing to a large moment being required at the hinge because of the large force applied by the yoke.

The present disclosure invention lies in the identification of this unexpected problem and the provision of its solution by reducing the friction, specifically between the cup cam follower and the yoke cam, by lubrication.

As described above, the applicant has surprisingly discovered that the problems of the increased force required to close the cover and the cover dislocating from its hinges can be solved by lubricating part of the internal surfaces of the inhaler: the yoke cam and cup cam follower.

The lubrication may be applied to reduce friction between the surfaces of the yoke cam and the cam follower which engage when the yoke cam urges the cup cam follower back to the dispensing port. Therefore, the lubricant may be applied on one or more of the surfaces of the yoke cam and the cup cam follower which engage (or are contactable in use).

The cup may be directly attached to the cup cam follower, or the cup may comprise a cup sled which guides the cup through the channel, wherein the cup cam follower is attached to the sled.

The yoke cam and the cup cam follower are typically made of a plastics material. The yoke cam can comprise a polyoxymethylene polymer. Examples of commercial products include POM Hostaform® MT8U01, MT8U03 or S9243 XAP2 and Tenac® LA541 or C LV40, POM Hostaform® MT8F01, Delrin® SC699 NC010 or Kepital® TS-25HN/25. Preferably the plastics material is a polytetrafluoroethylene-containing plastics, for example POM Hostaform® MT8F01.

The cup cam follower can comprise a polyester, for example polybutylene terephthalate. An example of a commercial product is Celanex® 2401 MT.

The surfaces of the yoke cam and/or the cup cam follower can be lubricated in a variety of ways, and suitable lubricants are known to the person skilled in the art. The term lubricated is intended to have broad meaning and include application of any lubricant or other adaptation of the surface of the components in order to reduce their coefficient of friction (which can be measured by the person skilled in the art).

| In one ~~example embodiment~~ the yoke cam is lubricated.

| One ~~example embodiment~~ of the ~~disclosure invention~~ involves lubrication by the application of a surface coating.

The surface coating may be a surface coating of oil, and in particular a coating of a siloxane. One particular siloxane that can be mentioned is polydimethylsiloxane. Two suitable medical grade commercial products including polydimethylsiloxane are Dow Corning 360 medical fluid and Dow Corning 365 Emulsion.

The siloxane can be applied to the component in any way. For example, by spraying the component or dipping the component in the siloxane. The component may subsequently need to be dried, for example if the siloxane is applied as an emulsion. Preferably, the oil/siloxane is applied by metering a droplet (e.g. from a syringe) directly on to the desired surface.

Alternatively, the surface coating may be a surface coating of soap or stearic acid.

A second ~~example embodiment of the disclosure invention~~ involves lubrication by addition of a material additive.

In one example of the addition of a material additive, the yoke cam and/or the cup cam follower comprises a plastics material and the material additive in the plastics is a slip additive.

A slip additive is a plastics material modifier that acts as an internal lubricant. The slip additive is added to the plastics material during manufacture and extrudes to the surface of the plastics material during and immediately after processing thereby reducing friction and improving slip at the surface of the plastic.

The slip additive can be a siloxane. Siloxanes can be added to the plastics material by a mixing process which is compounded or as a masterbatch. An example of a siloxane masterbatch is DOW CORNING MB40006 which comprises (in wt%) 40.0 - 70.0% trioxane-dioxolene copolymer, 30.0 - 60.0% dimethylvinyl-terminated dimethyl siloxane, and 1.0 - 5.0% polymethylene/acetal copolymer.

Preferably the plastics material is a polytetrafluoroethylene-containing plastics material, for example POM Hostaform® MT8F01, and the slip additive is a siloxane.

Typically, the slip additive is added to the plastics material at from 1 to 10 wt%, preferably from 3-7 wt%. In one ~~example embodiment~~ the slip additive is added at approximately 5 wt%.

In one ~~example embodiment~~, the DPI additionally comprises at least one cover cam mounted on the mouthpiece cover and movable with the cover between open and closed positions, wherein the cover cam includes at least a first and second cover cam surfaces;  
and the yoke includes yoke cam followers which are biased against the cam surfaces by an actuation spring;  
wherein the cover cam surfaces are arranged such that the yoke cam followers successively engage the first cover cam surface when the cover is closed, and the second cover cam surface when the cover is opened;

and the first cam surface is spaced further from the hinge than the second cam surfaces;  
and therefore the yoke cam followers are moved by the actuation spring from the first to the second cover cam surfaces as the cover is opened and thereby the yoke is moved from the second to the first position;  
and the yoke cam followers are moved against the actuation spring from the second to the first cover cam surfaces as the cover is closed and thereby the yoke is moved from the first to the second position.

Preferably the cover cam includes an additional intermediate cover cam surface between the first and second cover cam surfaces wherein the yoke cam followers are moved by the actuation spring from the first to the intermediate to the second cover cam surface as the cover is opened and the yoke cam followers are moved against the actuation spring from the second to the intermediate to the first cover cam surface as the cover is opened.

The ~~disclosure invention~~ also provides a dry powder inhaler comprising a moving component which is:

- made from a plastics material which includes a slip additive; or
- at least partially coated with an oil, soap or stearic acid.

The moving component can be a yoke cam and/or a cup cam follower as described above. Further, the moving component may be made of the materials described above, and lubricated in the manners described above.

### **Brief Description of the Drawings**

Specific embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Fig. 1 shows the DPI;

Fig. 2 shows the inside of the DPI;

Fig. 3 shows the dose metering mechanism of the DPI;

Figs. 4 and 5 show the cover of the DPI and the cover cam of the DPI;

Figs. 6-8 show the movement of the cup to the dispensing port on closure of the cover;

Figs. 9-11 show the movement of the cup away from the dispensing port to the delivery passageway on opening the cover;

Fig. 12 shows an unlubricated DPI for which the hinge has become dislocated;

Fig 13 shows the movement of the cup cam follower along the yoke cam;

Figs. 14-15 show the load required to open and close the cover of various DPIs;