(b) a water-soluble weak base, such as a phosphate; and

(c) a compound which is a weak acid, which acid is presented in intimate mixture with the microparticles of alfentanil or salt thereof.

Such compositions are referred to hereinafter as "the compositions of the disclosure".

In a first aspect, there is provided a pharmaceutical composition suitable for sublingual delivery, as well as rapid release of alfentanil therefrom and/or rapid uptake of alfentanil through the oral mucosa, which comprises a mixture comprising:

(a) microparticles of alfentanil, or a pharmaceutically acceptable salt thereof, which microparticles are presented on the surfaces of larger carrier particles;

(b) a weak base; and

(c) a compound which is a weak acid, which acid is presented in intimate mixture with the microparticles of alfentanil or salt thereof, by being presented either:

(1) within the carrier particles, such that said carrier particles comprise a composite of:

(i) said acid material; and

(ii) another carrier particle material; or

(2) upon the surfaces of the carrier particles.

In another aspect, there is provided a process for the preparation of a composition as defined above, which comprises dry mixing carrier particles with alfentanil or salt thereof.

In another aspect, there is provided a composition as defined above for use in the treatment of pain.

In another aspect, there is provided the use of a composition as defined above for the manufacture of a medicament for the treatment of pain.

In another aspect, there is provided ~~a composition or~~ use as defined above, wherein the treatment of pain comprises sublingual administration to a human patient in need of treatment of a pharmaceutical composition comprising between

**Claims**

1. A pharmaceutical composition suitable for sublingual delivery, as well as rapid release of alfentanil therefrom and/or rapid uptake of alfentanil through the oral mucosa, which comprises a mixture comprising:

(a) microparticles of alfentanil, or a pharmaceutically acceptable salt thereof, which microparticles are presented on the surfaces of larger carrier particles;

(b) a weak base; and

(c) a compound which is a weak acid, which acid is presented in intimate mixture with the microparticles of alfentanil or salt thereof, by being presented either:

(1) within the carrier particles, such that said carrier particles comprise a composite of:

(i) said acid material; and

(ii) another carrier particle material; or

(2) upon the surfaces of the carrier particles.

2. A composition as claimed in Claim 1, wherein the acid is citric acid.

3. A composition as claimed in any one of the preceding claims, wherein the weak base comprises a phosphate, such as trisodium phosphate.

4. A composition as claimed in any one of the preceding claims, wherein the carrier particles comprise mannitol.

5. A pharmaceutical composition as claimed in any one of the preceding claims, which further comprises a disintegrant.

6. A composition as claimed in Claim 5, wherein the disintegrant is a superdisintegrant selected from croscarmellose sodium, sodium starch glycolate, crosslinked polyvinylpyrrolidone or a mixture thereof.

7. A composition as claimed in any one of the preceding claims wherein the weak base is water-soluble.

8. A composition as claimed in any one of the preceding claims which is in the form of a tablet suitable for sublingual administration.

9. A process for the preparation of a composition as defined in any one of Claims 1 to 8, which comprises dry mixing carrier particles with alfentanil or salt thereof.

10. A process for the preparation of a composition as defined in Claim 8, which comprises directly compressing or compacting a composition as defined in any one of Claims 1 to 6.

11. A composition as defined in any one of Claims 1 to 8 for use in the treatment of pain.

12. The use of a composition as defined in any one of Claims 1 to 8 for the manufacture of a medicament for the treatment of pain.

13 ~~A composition as claimed in Claim 11, or~~ The use as claimed in Claim 12, wherein the pain is moderate to severe pain.

14. The ~~A composition or~~ use as claimed in Claim 13, wherein the treatment is short term.

15. The ~~A composition or~~ use as claimed in Claim 13 or Claim 14, wherein the pain is associated with a diagnostic, a surgical or a care-related procedure.

16. The ~~A composition or~~ use as claimed in Claim 15 wherein the composition is administered not more than about 20 minutes prior to the procedure.

17. ~~A composition or~~The use as defined in any one of Claims 1~~2~~ to 16, wherein the treatment of pain comprises sublingual administration to a human patient in need of treatment of a pharmaceutical composition comprising between about 30 µg and about 3,000 µg of alfentanil or a pharmaceutically acceptable salt thereof, wherein said administration gives rise to a plasma concentration-time curve after said administration that possesses:

(I) a $t_{max}$ (time to maximum plasma concentration) that is between about 10 and about 25 minutes after said administration; and/or

(II) a $t_{last}$ (time to last measurable plasma concentration) that is not more than about 300 minutes after said administration; and, optionally,

(III) a $C_{max}$ (maximum plasma concentration) that is between about 10 and about 100 ng per mL of plasma.

~~18. A composition or use as claimed in Claim 17 which comprises administration of a composition as defined in any one of Claims 1 to 8.~~