PRE-GRANT REPRESENTATION BY WAY OF OPPOSITION
UNDER SECTION 25(1) OF THE PATENTS ACT
1970(39 OF 1970) AND RULE 55 (1) OF THE RULES
AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005

The Patent Controller,
Kolkata.

**Re: Patent Application No. 2044/CAL/1997 filed on 29 October 1997 titled "Pharmaceutical Compositions"**

**STATEMENT OF FACTS/ EVIDENCE**

1. The Indian Network of Positive People ("INP+"), a community-based, non-profit organisation, registered as a society under the Tamil Nadu Societies Registration Act in May 1997, and the Manipur Network of Positive People ("MNP+"), a community-based, non-profit organisation, registered under the Societies Registration Act of 1989 in December 1998, (collectively, the "Opponents") hereby make a representation by way of opposition under § 25(1) of the Patent Act 1970, as amended by the Patents (Amendment) Act, 2005 (the "Act") against the grant of patent application, titled: "Pharmaceutical Compositions," made by Applicant Glaxo Group Limited (the "Applicant"), bearing Indian patent application No. 2044/CAL/1997 filed on 29 October 1997 (the "Application"). This representation is proper under § 25(1) of the Act as the application has been published but a patent has not been granted. Specifically, this representation is brought under the grounds as stated in § 25(1)(b), (e), (f) and (g) of the Act.

2. INP+ is a national community-based organization representing the needs of people living with HIV/AIDS ("PLHAs"). INP+ is the national level organization and has under its umbrella many organizations at the State level. MNP+ is the state of Manipur's state-level member network of INP+. The essence of both INP+ and MNP+ is to provide a voice for PLHAs at the local, regional and national levels in order to facilitate systemic change in critical areas such as care and support, access to treatments and addressing issues of discrimination facing PLHAs in Indian society. Of particular concern to Opponents is the impact of the new product patent regime on PLHAs' access to safe, effective and affordable HIV/AIDS treatments. The Opponents are opposing the above-mentioned application for a patent under section 25(1) of the Patents Act.

3. The patent application was filed at the Patent Office in Kolkata, therefore, the Patent Controller has the jurisdiction to hear this pre-grant opposition in Kolkata. Opponents hereby request a hearing as per provisions under Rule 55(1) of the Patent Rules, 2005.

4. The present Application relates to a treatment for HIV, a virus that is causing untold harm and misery in India and throughout much of the developing world. While HIV, in part through the availability of treatments like the one at issue here, has become a chronic but manageable lifelong condition for many in the developed world, it remains a death sentence for the millions who cannot afford or otherwise access treatment. Patent protections granted to treatments for HIV only exacerbate this problem. Patents grant the patent owner a 20-year monopoly, during which the owner is free to set prices at levels impossibly beyond reach for the vast majority of those who are in desperate need of treatment.

5. India's Patents (Amendment) Act, 2005 was passed in order to bring India into compliance with its TRIPS obligations under the WTO, and introduced for the first time a 20-year product patent regime in this country. India, however, is also a signatory to the Doha Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration"), which states, in part, "we affirm that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health ***and, in particular, to promote access to medicines for all***," (emphasis added).

6. In part due to the recognition of its obligations under the Doha Declaration, Parliament passed the Act with a few important provisions aimed at ensuring that a product patent regime would not harm public health. One of the most important is § 3(d) of the Act, a provision designed to discourage the pernicious but all-too-common practice of "evergreening," whereby pharmaceutical companies artificially extend the life of their monopolies by patenting trivial improvements to already existing drugs. Declaring that "a new form of a known substance which does not result in the enhancement of the known efficacy of that substance," and the discovery of a "new use for a known substance" are ***not*** inventions under the meaning of the Act, Parliament expressed through § 3(d) its unequivocal rejection of evergreening.

7. The present Application falls squarely in the category of "inventions" that Parliament intended in rejecting when it enacted § 3(d). The original patents for the active ingredients of this drug have either expired or were granted prior to 1995, when India first incurred its obligations under the WTO. The sole "improvement" at issue is the addition of a pharmacologically inactive ingredient that does nothing to improve the drug's efficacy. Granting the current Application a patent will do nothing but further enrich the Applicant at the expense of human lives.

8. The Opponents humbly submit that the obligation to "promote access to medicines for all" has been incorporated into the Act by Parliament, and that the Act, whenever possible, can and must be interpreted in a manner that is consistent with the Doha Declaration's binding promise, as it is this Office that ultimately makes the decision that will determine whether millions of people will have access to essential medicines. The Opponents respectfully request that the Patent

Office keep the Doha Declaration in mind as it examines the present Application and interprets the applicable law.

## GROUNDS

9. The Opponent has closely studied the specification and claims made by the Applicant in the Application and strongly believes that the invention is not patentable under the following grounds of s25(1) of the Act:

    a. s25(1)(b)(ii) - that the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim elsewhere in any other document.

    b. s25(1)(e) – that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step having regard to the matter published as mentioned in clause (b) or having regard to what was used in India before the priority date of the applicant's claim.

    c. s25(1)(f) – that the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act, in particular under sections 3(d) and 3(e).

    d. s25(1)(g) – that the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed.

    Accordingly, as permitted under s25(1) of the Act, which allows an opposition to be filed by any person after publication but before the grant of a patent, and Rule 55(1) of the Rules, the Opponent submits its opposition to the Application on the grounds set out below.

10. The Applicant has failed to meet its burden of showing that the alleged invention described in the Application is entitled to a patent under the Act. Simply put, the present Application relates to little more than the addition of a widely known class of inert, pharmacologically inactive substances to a drug combination that has been known, used and prescribed *for years* prior to the present Application. Specifically, the alleged invention relates to the addition of a glidant – a class of substances the Applicant admits has been widely used in the pharmaceutical industry in the manufacture of tablets (*See* Application, p. 3, lines 6-17; p. 7, lines 13-29) – to a tablet containing lamivudine and zidovudine, two known treatments for HIV, the combination of which was disclosed in **1992** in **European Patent**

**No. 0513917** (the "'917 patent," attached hereto as **Exhibit A**), and which has been prescribed in combination since 1995. *See* Application, p. 2, lines 21-27.

11. Despite the Applicant's admissions that the use of glidants is known and that the combination of lamivudine and zidovudine is known, the Applicant nonetheless claims that the alleged invention is patentable. Specifically, the Applicant's claims can be summarised as follows:

    (a) Claims 1 and 19-22 all relate to a pharmaceutical composition comprising of lamivudine, zidovudine and a pharmaceutically acceptable glidant.

    (b) Claims 2–13 are dependent upon Claim 1, and specify the range of possible properties of the pharmaceutical composition described in Claim 1.

    (c) Claims 14-16 relate to the method for using a glidant to increase and maintain the homogeneity of a pharmaceutical composition.

    (d) Claims 17–18 are dependent upon Claims 1-13 and relate to the use of the alleged invention for treating viral infections.

    (e) Claim 23 is a process claim dependent upon Claims 1-13.

    (f) Claims 24-25 are omnibus claims.

12. Thus, the claims of the Application all directly or indirectly relate to the addition of a glidant to an already-known pharmaceutical combination. However, the mere addition of a glidant – a class of substances that the Applicant admits is known in the art – is insufficient to render the alleged invention patentable under the Act. This is because the mere addition of a glidant to a known combination is: (i) at most, a mere "discovery" of a *new form* of a known substance and is thus not an invention under § 3(d) of the Act; (ii) at most, the mere "discovery" of a *new use* for a known substance and is thus not an invention under § 3(d) of the Act; (iii) a "mere admixture" and is thus not an invention under § 3(e) of the Act; (iv) anticipated by the disclosures contained in the '917 patent and thus lacks novelty; and (v) obvious to one skilled in the art. Furthermore, the Application fails because it fails to sufficiently describe the alleged invention, as required under §§ 10(4) and 10(5) of the Act. Each of these separate and independent grounds for denying the present Application is discussed in further detail below.

***The Alleged Invention Is Not An Invention Under § 25(1)(f) and § 3(d) Of The Act Because It Is The Mere "Discovery" Of A New Form Of A Known Substance.***

***13.*** The alleged invention is not patentable under the Act because it is, at most, the mere "discovery" of a new form of a known substance. Under § 3(d) of the Act, the "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" is not an invention within the meaning of the Act. The accompanying Explanation to § 3(d) states, "For the purposes of this clause, salts, esters…***combinations*** and other derivatives

of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy," (emphasis added). Because the alleged invention claims to be and is in fact nothing more than a ***combination*** of already-known substances, and because the Applicant has made no attempt to meet its burden of showing that this combination results in a product that results in an "enhancement of the known efficacy," it is not an invention within the meaning of the Act under § 3(d).

*14*. The Applicant unequivocally admits that the lamivudine and zidovudine are known, both individually and in combination. The Applicant states, "Two of the many compounds which are commonly included in multiple-drug treatment regimens for HIV are zidovudine and lamivudine. Lamivudine…is a synthetic nucleoside analogue, chemically known as (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-IH-pyrimidin-2-one…Zidovudine, chemically known as 3'azido-3'-deooxythymidine, is a pyrimidine nucleoside analogue… *See* Application, p. 2, lines 3-20. The Applicant further states, "In November of 1995, the FDA granted accelerated approval for the use of lamivudine in combination with zidovudine for first-line treatment of HIV-infection in adults and children." *Id*., lines 21-23. Furthermore, the '917 patent specifically disclosed in 1992 – five years prior to the date of the present application – a combination of 3'azido-3'-deooxythymidine [zidovudine] with (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-IH-pyrimidin-2-one [lamivudine]. *See* Exhibit A, p. 11 (claim 6). Thus, it is beyond debate that lamivudine and zidovudine, both individually and in combination, are known substances.

***15.*** Likewise, the Applicant admits that "[g]lidants are substances that have traditionally been used to improve the flow characteristics of granulations and powders by reducing interparticulate friction." *See* Application, p. 3, lines 6-7; *see also* p. 7, lines 13-15. Far from being new or heretofore unknown substances, glidants are generally simple, everyday compounds, such as silicon dioxide, corn starch, calcium carbonate, or starch. Indeed, the list of "pharmaceutically acceptable" glidants claimed in the Application are the following: "silicon dioxide, colloidal silicon dioxide, fumed silicon dioxide, sodium aluminosilicate, calcium silicate, powdered cellulose, microcrystalline cellulose, corn starch, sodium benzoate, calcium carbonate, magnesium carbonate, asbestos free talc, metallic stearates, calcium stearate, magnesium stearate, zinc stearate, stearowet C, starch, starch 1500, magnesium lauryl sulfate, or magnesium oxide." *See Id.*, p. 14, lines 10-17. The Applicant does not and cannot make any claim that *any* of these substances are unknown. Indeed, the Application itself refers to a prior art reference that specifically identifies such substances as "commonly used glidants," and even provides a recommended range of concentration values. *See* Lieberman, Lachman & Schwartz, Pharmaceutical Dosage Forms: Tablets, Vol. 1, p. 177-178 (1989), attached hereto as **Exhibit B**. Glidants, as a class of substances, as well as the individual glidants over which the Applicant claims ownership in the Application, are known substances.

*16.* As the foregoing shows, all of the substances contained in the present Application are known. Nevertheless, the Applicant in Claim 1 purports to stake ownership over the following: "A pharmaceutical composition comprising: (i) a safe and therapeutically effective amount of lamivudine or a pharmaceutically acceptable derivative thereof; (ii) a safe and therapeutically effective amount of lamivudine or a pharmaceutically acceptable derivative thereof; and (iii) a pharmaceutically acceptable glidant." *See* Application, p. 14, lines 3-9. It is abundantly clear that each of the substances in the claimed combination is a known substance. As such, under § 3(d) of the Act, the combination of these known substances can be considered an invention only if the Applicant can show that the combination results in the "enhancement of the known efficacy" of the product. Applicant has failed to meet this burden.

17. In order to meet its burden under § 3(d), the Applicant is required to present evidence that the claimed invention (i.e., the lamivudine-zidovudine combination plus a glidant) represents an enhancement in the known efficacy over the previously known substance. (i.e., the lamivudine-zidovudine combination). The Applicant does not and cannot satisfy this requirement. The Applicant admits that the only *active* ingredients in the claimed invention are lamivudine and zidovudine. *See*, e.g., Application, p. 1, lines 6-8; p. 3, lines 23-26. However, the therapeutic efficacy of the active ingredients were already known and disclosed in the '917 patent and in the subsequent clinical trials of that invention. *See* Exhibit A, p. 4, lines 20-37 ("We have now found that [lamivudine] exhibits unexpected advantages when used in combination with known inhibitors of HIV replication… Particularly preferred as the inhibitor of HIV replication is ddI or, especially, [zidovudine]"). The Application itself states, "Lamivudine exhibits unexpected advantages when used in combination with known inhibitors of HIV replication. In particular, lamivudine shows synergistic antiviral effect when used in combination with zidovudine. In controlled clinical trials, combination therapy with lamivudine and zidovudine delayed the emergence of zidovudine-resistant mutations of HIV." *See* Application, p. 2, lines 23-27. Nowhere in the Application does the Applicant even attempt to show that the addition of a pharmacologically inert glidant represents an improvement in therapeutic efficacy over the combination disclosed in the '917 patent.

18. The sole "advantage" that the Application discloses with respect to the addition of a glidant is the assertion that glidants "can be used to increase and aid blend composition homogeneity. The novel compositions of the present Invention use glidants to effect and maintain homogeneity of active ingredients during handling prior to tablet compression." *See* Application, p. 3, lines 19-22. In other words, the addition of a glidant during the manufacturing process is, at most, a helpful tool in the mass-production of a particular dosage form of the active ingredients. This is insufficient to meet the "known efficacy" requirement under § 3(d).

19. This alleged "improvement" bears no relation to the ultimate therapeutic efficacy of the active ingredients. It is, at most, a tool that may facilitate: (i) the *mass* production (ii) of a *particular* dosage form of the active ingredients (i.e., the tablet

form). However, there is no sound reason why the relevant comparison should be between the therapeutic efficacies of a mass-produced tablet using a glidant versus that of a mass-produced tablet without a glidant. The Applicant has put forth no evidence to show that the therapeutic efficacy of a mass-produced tablet with a glidant is greater than that of, say, the zidovudine-lamivudine combination in an aqueous suspension *without* a glidant, or the same combination with a glidant but manufactured through different means. Parliament, in its considered wisdom, could have drafted § 3(d) so that the relevant standard was not an improvement in the "known efficacy," but a mere improvement in "mass manufacturability." Given that Parliament declined to do so, the alleged "improvement" claimed in the present Application fails to pass muster, and cannot be considered an invention under Indian law.

***The Alleged Invention Is Not An Invention Under §25(1)(f) and § 3(d) Of The Act Because It Is The Mere "Discovery" Of A New Use For A Known Substance.***

20. Separate from and independent of the above analysis, § 3(d) of the Act provides another reason to reject the present Application. Section 3(d) also states, "…the mere discovery of any new property or new use for a known substance" is not an invention within the meaning of the Act. As discussed above, the Applicant admits that glidants have been known and used by those skilled in the art for years prior to the present Application. *See* Application, p. 7, lines 13-29. The present Application, however, claims that it has discovered a new use for such substances: "…glidants may be used to reduce segregation of active ingredients and thus improve the homogeneity of pharmaceutical compositions, powders and granulates." *See* Id., p. 8, lines 5-9. The Applicant claims that it accomplishes this new use by introducing the glidant in the initial mixture rather than the traditional practice of adding the glidant immediately prior to tablet compression. *See* Id., lines 19-24.

21. Even assuming the truth of these claims, the present Application cannot be considered an invention under § 3(d) of the Act. As demonstrated above, the Applicant has admitted that *all* of the components in the alleged invention are known substances. The sole "innovation" in the Application is the alleged discovery of a new use of a known class of substances achieved by introducing the substances earlier in the manufacturing process. Under the plain text of § 3(d), "the mere discovery of any…new use…for a known substance" shall not be an invention under the Act. The Applicant has not claimed that any of the glidants it specifically mentions in the Application are novel substances. Given this, the alleged invention can be considered, at most, the discovery of a new use of a known substance, and is thus unpatentable as a matter of law under § 3(d).

***The Alleged Invention Is A Mere Admixture And Is Unpatentable Under § 25(1)(f) and §3(e) Of The Act.***

22. Under § 3(e) of the Act, "a substance obtained by the mere admixture resulting only in the aggregation of the properties of the components thereof" is not an

invention within the meaning of the Act. For all of the reasons hereinabove stated, the present Application fails on this ground as well. The only active ingredients in the alleged invention are substances that were known and disclosed in the '917 patent, and the glidant is a pharmacologically inert substance that adds no therapeutic efficacy to the final product. As such, the "substance obtained" under the present Application is nothing more than the "aggregation of the properties" of its constituent components. Whatever synergistic effects the final product may exhibit arise not from the addition of a glidant, but from the combination of lamivudine and zidovudine, the effects of which were disclosed in the '917 patent and are admitted as known by the Applicant. For these reasons, the present Application is a mere admixture and not an invention under § 3(e) of the Act.

***The Alleged Invention Is Anticipated by A Prior Publication under 2(j), 25(b)(ii) and 25(1)(f)***

23. Claim 1 and its dependent Claims 2-13 and 17-25 of the present Application fail on the additional ground that they lack the requisite novelty for patentability. Under 25(1)(f) the Application should be denied if any claim of the complete specification is not an invention within the meaning of this Act. Under Section 2(j), an invention is defined as a new product or process involving an inventive step and capable of industrial application. Section 25(1)b)(ii) states that the Application may be denied if the invention so far as claimed in any claim of the complete specification has been published before the priority date of the claim, in India or elsewhere, in any other document. Thus, if a publication published prior to the present Application discloses the claimed invention, then the Application lacks novelty, is not a new product or invention and, therefore, must be rejected.

***24.*** In the present case, the '917 patent specifically discloses the combination of lamivudine and zidovudine "together with one or more pharmaceutically acceptable carriers…" *See* Exhibit A, p. 6, lines 3-4, *see also* p. 11, Claims 8-9. The patent further discloses that the combination could be in tablet form, which may contain "conventional excipients, such as binding agents, fillers, lubricants, disintegrants or wetting agents." *See* Id., lines 17-18. Although the term "glidant" is never specifically disclosed in the '917 patent, it would be immediately evident to one skilled in the art that a glidant is merely a type of excipient, and something that is commonly included in tablet dosage forms of various drugs. *See, e.g.,* United Stated Food and Drug Administration, Center for Drug Evaluation and Research, *Guidance for Industry, Immediate Release Solid Oral Dosage Forms*, November 1995, p. 7, attached hereto as **Exhibit C**. As such, to one skilled in the art, the disclosures contained in the '917 patent would be readily understood as disclosing a pharmaceutical composition containing the lamivudine-zidovudine combination with a pharmaceutically acceptable glidant. Therefore, Claim 1 and its dependent Claims 2-13 and 17-25 of the present Application all fail for lack of novelty.

***The Alleged Invention Is Obvious To A Person Skilled In The Art Under §25(1)(e).***

25. For all of the reasons stated above, Claim 1 and its dependent Claims 2-13 and 17-25 of the present Application also fail because they lack the inventive step required for patentability. Furthermore, Claims 14-16 also fail because they are obvious someone skilled in the art. Under § 2(ja) of the Act, "inventive step" is defined as "a feature of an invention that involves technical advance as compared to the existing knowledge…that makes the invention not obvious to a person skilled in the art."

***26.*** For the reasons already stated, it would have been obvious to a person skilled in the art, given the disclosures contained in the '917 patent, to include a glidant in the manufacturing process for a tablet form of the product. Moreover, the Applicant admits that glidants are widely used throughout the pharmaceutical industry. *See* Application, p. 3, lines 6-7; *see also* p. 7, lines 13-15. Indeed, Lieberman, et al disclosed in 1989 not only a list of commonly used glidants, but their recommended concentrations, which range from 0.1% - 10.0%. *See* **Exhibit B** at 178. Therefore, a pharmaceutical composition comprising of the known combination of lamivudine and zidovudine and glidant would be obvious to one skilled in the art. Furthermore, the relative amounts of the active ingredients and glidants to be included in the composition would also be obvious to one skilled in the art. Finally, that this composition would be useful for "treating, reversing, reducing, or inhibiting" retroviral infections – particularly HIV – would be obvious to one skilled in the art. As such, Claim 1, along with its dependent claims 2-13 and 17-25 all fail because they lack the inventive step required for patentability.

***27.*** The sole "innovation" that the Applicant claims with respect to the use of glidants is the alleged "discovery" that glidants can be used to "improve the homogeneity of pharmaceutical compositions, powders and granulates." *See* Id., p. 8, lines 5-9; Claims 14 -16. The homogeneity of the compositions is important to ensure that the "ingredients are substantially evenly dispersed throughout that part of the finished formulation which includes lamivudine, zidovudine and the glidant." *See* Id., p. 6, lines 1-2. Presumably, this is important to ensure that accurate dosages of the active ingredients are contained in the final product.

***28.*** It is, however, well-known in the art that the addition of a glidant can be useful in improving dosage accuracy. *Pharmazeutische Technologie, Thieme Verlag Stuttgart*, 1991, pp. 259-260 (attached hereto as **Exhibit D**; official English translation attached hereto as **Exhibit E**) teaches that glidants have numerous benefits, including improving dosage accuracy. Thus, given the state of the art at the time, it would have been obvious to one skilled in the art to solve the problem of particle segregation through the introduction of a glidant. Moreover, given that numerous glidants, including the ones that the Applicant specifically mentions in Claims 15 and 16, were known in the industry, it would have been obvious to one skilled in the art to utilise one or more of these glidants to solve the alleged "problem" presented. Therefore, Claims 14-16, all of which relate to the method of maintaining composition homogeneity through the use of a glidant, are obvious, lack an inventive step, and should be denied.

***The Application Fails to Sufficiently Describe the Alleged Invention, and the Claims are not Fairly Based on the Matter Disclosed in the Specification Under Section §25(1) (g) and §10(4) and (5).***

29. The Applicant purports to have "invented" a method of solving the alleged "problem" of particle segregation through the addition of a glidant at a particular stage of the manufacturing process. However, the Application fails to sufficiently describe the alleged invention as required under § 10(4) of the Act. Furthermore, the vast majority of the claims have nothing to do with the alleged solution to the "problem" of particle segregation, and thus are not "fairly based on the matter disclosed in the specification," as required under § 10(5) of the Act.

***30.*** The alleged "problem" that the Applicant claims to solve is the segregation of lamivudine and zidovudine particles "during material handling prior to tablet compression." *See* Application, pp. 2-3. The alleged "solution" that the Application discloses is the addition of the glidant "in the initial mixture to improve and maintain homogeneity during handling prior to compression." *See* Id. at 8, lines 19-24. However, § 10(5) of the Act requires that the "claim or claims…***be fairly based on the matter disclosed in the specification***," (emphasis added). This means that the claims must correspond to the specific technical contribution described in the specification, thus narrowly tailoring the monopoly granted by a patent to the actual invention, and not over subject matter that goes beyond it.

***31.*** Thus, even assuming the existence of this alleged "problem" and the validity of the Applicant's alleged "solution," the vast majority of the claims – namely, Claims 1-13 and 17-25 – bear no relation whatsoever to the alleged solution to the problem of particle segregation. Rather, these overbroad claims simply relate to the addition of a glidant – ***a concept that the Applicant repeatedly admits is known and obvious in the art*** (*see* Application, p. 3, lines 6-17; p. 7, lines 13-29) – without any reference whatsoever to the alleged "inventive concept" of adding a glidant at a specific point during the manufacturing process to solve the problem of particle segregation. As such, Claims 1-13 and 17-25 are not "fairly based on the matter disclosed in the specification" and must be denied.

*32.* Moreover, Claims 14-16, which do arguably relate to the "inventive concept" of achieving composition homogeneity through the use of glidants, nonetheless fail to sufficiently describe the alleged invention as required under § 10(4) of the Act. Section 10(4) requires that every complete specification: "(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed; (b) describe the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; (c) end with a claim or claims defining the scope of the invention for which protection is claimed; and (d) be accompanied by an abstract to provide technical information on the invention. Claim 14 stakes ownership, without any further elaboration, over a "method for increasing and maintaining the homogeneity of a pharmaceutical composition by including a safe and effective

amount of a pharmaceutically acceptable glidant." *See* Application, p. 16, lines 8-10. Claims 15 and 16, which are dependent upon Claim 14, provide no further elaboration as to the precise method by which greater homogeneity is achieved. *Id*., lines 11-26. These disclosures, as well as the disclosures contained in the description, are insufficient under § 10(4) of the Act.

*33.* Because the Applicant admits that the use of glidants is known and obvious in the art, § 10(4) requires the Applicant to "fully and particularly describe" how its *particular* use of glidants constitutes an invention, and to "describe the best method of performing the invention." In other words, the Applicant is required to show, through a detailed description, that its particular method of using glidants results in a significant improvement in particle homogeneity over other known methods of using glidants. The Applicant has failed to do this.

*34.* The *only* description of the "invention" that the Applicant provides is in Example II, along with a naked assertion that "the present invention makes use of glidants in the initial mixture to improve and maintain homogeneity during handling prior to composition." *See* Application, p. 8, lines 22-24; pp. 12–13. The Applicant makes no attempt at showing that the addition of a glidant at a specific stage of the manufacturing process has any direct, causal relation to improved particle homogeneity. Furthermore, the Applicant provides no information from which a person skilled in the art could conclude that the addition of a glidant in a particular manner at a particular stage results in a measurable and significant improvement in particle homogeneity over other known methods. Under § 10(4) of the Act, the Applicant was required to submit such information. As such, Claims 14-16 all fail for lack of sufficient description under § 10(4).

**CONCLUSION**

35. Given all of the foregoing, Opponents hereby humbly request that the Patent Office reject the Application on the following grounds:

(a) The alleged invention is a "mere discovery of a new form of a known substance" and thus not an invention under § 3(d) of the Act;

(b) The alleged invention is a mere discovery of a "new use of a known substance" and thus not an invention under § 3(d) of the Act;

(c) The alleged invention is a "mere admixture" and thus not an invention under § 3(e) of the Act;

(d) Claim 1 and its dependent Claims 2-13 and 17-23 of the present Application fail for lack of novelty; and

(e) All of the Claims in the present Application fail for lack of inventive step.

(f) All of the Claims in the present Application fail for insufficient description.

36. Opponents further request that the Office grant a hearing as per Rule 55(1) of the Patent Rules.

**Respectfully submitted,**

On Behalf of the Indian Network of Positive People,

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K.K. Abraham Date

On Behalf of the Manipur Network of Positive People,

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Ratan Singh Date