UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Amneal Pharmaceuticals, LLC, Defendants.	Civil Action No. 14-CV-2758 (PAC)
Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (dba Zydus Cadila), Defendants.	Civil Action No. 14-CV-2760 (PAC)
Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Orient Pharma Co., Ltd., Defendants.	Civil Action No. 14-CV-2759 (PAC)

Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Sawai USA, Inc., and Sawai Pharmaceutical Co., Ltd., Defendants.	Civil Action No. 14-CV-5575 (PAC)
Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Apotex, Inc. and Apotex Corp., Defendants.	Civil Action No. 14-CV-7934 (PAC)
Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Lupin Ltd. and Lupin Pharmaceuticals, Inc., Defendants.	Civil Action No. 15-CV-3935 (PAC)

DEFENDANTS' PROPOSED FINDINGS AND CONCLUSIONS RE:

INAVALIDITY BASED ON INDEFINITENESS OF ASSERTED

"FORM A" CLAIMS UNDER SECTION 112 OF THE PATENT ACT

PRESENTED BY SAWAI

I. SCIENTIFIC BACKGROUND

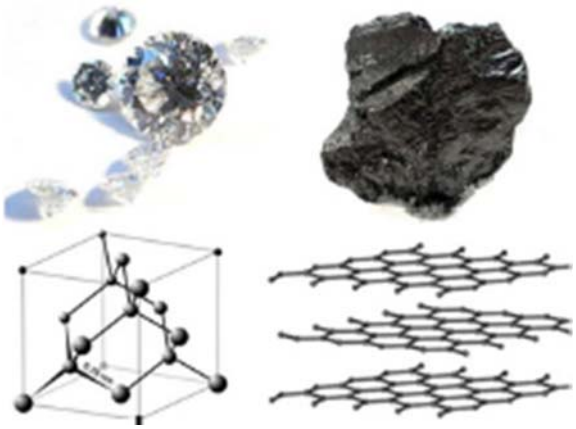
A. Crystalline Solids and Polymorphism

1. Crystalline solids contain atoms and molecules that are arranged in a long-range, repeating pattern in three-dimensional space. The internal structure (called the crystal structure) of a compound is determined by the position of the atoms or molecules relative to each other in three dimensions. The atoms and molecules within the crystal structure are held together by interactions between the atoms making up the substance.

2. Solids that are not crystalline have no long range order of the atoms and molecules that make up the solid. These materials are often referred to as amorphous solids. Glass is an example of an amorphous solid, in that the silicon dioxide molecules of glass lack that long-range three-dimensional order. Amorphous solids are generally less stable than crystalline solids.

3. For some solid substances, the atoms and molecules that make up the crystal structure can be arranged in more than one configuration in three-dimensional space. That is, the atoms or molecules can pack together in more than one way to produce different crystalline forms. The ability of atoms, molecules or ions to exist in more than one crystal form or structure is known as polymorphism, and the various different crystal forms of the same compound are known as *polymorphs*. The different polymorphs of a compound can have very different properties despite the fact that they are made of the same molecule. A familiar related example involving the different arrangement of the same atom is carbon, which exists both as graphite and as diamond depending on the atoms' three-dimensional arrangement. The different forms of

carbon are technically "*allotropes*," not polymorphs, but the example is no less applicable for this difference in nomenclature.



comparison of diamond (left) and graphite (right)

4. It is quite common for crystals of organic compounds including salt forms to have different polymorphs. These different polymorphs will have different physical and chemical properties. For example, different polymorphs can exhibit different melting points, solubilities, chemical stabilities, hygroscopicities, X-ray crystal structures and XRPD patterns (discussed below), among many other properties.

5. Different polymorphs can also exhibit different relative stabilities under different environmental conditions. For example, one polymorph of a substance may be stable at room temperature, while another is stable only at elevated temperatures. Generally, it is common for organic compounds that exhibit polymorphism to have more than one form that is stable enough to be isolated and stored at room temperature. Although a compound may be able to crystallize into many polymorphs that are relatively stable, only one of those forms will be the most stable of the group under a given set of conditions. When stable and unstable polymorphic forms are

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