

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC,
Petitioner,

v.

ADAPT PHARMA OPERATIONS LIMITED, and
OPIANT PHARMACEUTICALS, INC.,
Patent Owners.

Case IPR2019-00685
U.S. Patent No. 9,211,253

PATENT OWNERS' SURREPLY

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Nalox-1's Reply introduces brand-new theories that it claims, without a hint of irony, support obviousness, even though it took Nalox-1 over a year to arrive at them. Nalox-1's new theories fare no better than its old ones. The Board should reject them all.

Particularly astonishing is how frequently Nalox-1 sets about trying to discredit its own references. An obviousness case should have the POSA follow the teachings of its references. Here, at every turn, Nalox-1 would have the POSA read Wyse and HPE and do precisely what they instruct *not* to do—try to achieve high and fast naloxone levels, use BZK, and combine it with EDTA.

In reply, Nalox-1 attempts to discredit Wyse's BZK teachings based on a new and incorrect theory that BZK "could not cause the naloxone degradation reported in Wyse." Reply 2. Wyse did not conclude that, and Nalox-1's evidence does not support it. Nalox-1's expert contends only that BZK cannot "directly" react with naloxone to form a particular naloxone degradant—a far cry from Nalox-1's blanket assertion of impossibility. And the POSA would know that BZK could *indirectly* cause degradation.

Nalox-1 also claims for the first time that the POSA would ignore Wyse and undertake extensive testing to find some alternate "root cause" of the degradation—one Nalox-1 is glaringly unable to identify. Nalox-1's suggestion that the POSA would try to pull BZK from the reject pile is hindsight at its worst.

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