IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | |
|---|---|
| HOSPIRA, INC.,<br><br>Plaintiff,<br><br>v.<br><br>AMNEAL PHARMACEUTICALS LLC<br><br>Defendant. | Civil Action No. 15-697-RGA |

**JOINT CLAIM CONSTRUCTION CHART**

Pursuant to Paragraph 8 of the Court's September 22, 2015 Scheduling Order (ECF No. 13) and the Stipulation and Amended Scheduling Order entered on January 5, 2016 (ECF No. 35), Hospira, Inc. and Amneal Pharmaceuticals LLC (collectively, the "Parties") respectfully submit this Joint Claim Construction Chart for U.S. Patent Nos. 8,242,158 (the "'158 patent") (Ex. 1); 8,338,470 (the "'470 patent") (Ex. 2); 8,455,527 (the "'527 patent") (Ex. 3); and 8,648,106 (the "'106 patent") (Ex. 4). In addition, the following documents are attached as Exhibits 5-10:

| | |
|---|---|
| Exhibit 5: | Patent File History of U.S. Application No. 13/343,672 Response to Office Action, March 13, 2012 |
| Exhibit 6: | Patent File History of U.S. Application No. 13/343,672, Petition to Make Special, Showing of Support for Each Claim Limitation, January 4, 2012. |
| Exhibit 7: | Patent File History of U.S. Application No. 13/541,524, Petition to Make Special, Showing of Support for Each Claim Limitation, July 3, 2012. |
| Exhibit 8: | Patent File History of U.S. Application No. 13/678,148, Petition to Make Special, Showing of Support for Each Claim Limitation, November 15, 2012). |
| Exhibit 9: | Patent File History of U.S. Application No. 13/541,524, Response to Non-Final Office Action |
| Exhibit 10: | U.S. Patent No. 4,910,214 |

The Parties' agreed and proposed constructions reflected in the Joint Claim Construction Chart are expressly limited to the claims that have been identified as asserted claims in this case, and they should not be taken as an admission or concession concerning construction of the same or similar language in the context of a different patent. Discovery is still in its early stages, and is ongoing. The Parties reserve the right to supplement, amend, or modify their proposed constructions and intrinsic evidence upon discovery of additional evidence and after conducting additional analysis.

## AGREED CONSTRUCTION

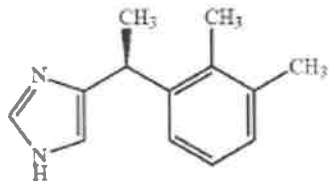
| Term(s)/Phrase(s) | Claims-in-issue | Agreed Construction |
|---|---|---|
| "effective amount" | 8,455,527: Claim 1 | *Amount sufficient to produce the desired effect.* |

## DISPUTED CONSTRUCTIONS

| Term(s)/Phrase(s) | Claims-in-issue | Hospira's Construction | Amneal's Construction |
|---|---|---|---|
| "dexmedetomidine" | 8,242,158: All claims<br>8,338,470: All claims<br>8,455,527: All claims<br>8,648,106: All claims | *Substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base or pharmaceutically acceptable salt.*<br>'158 patent at 3:21-47; *see also* 5:46-6:8; 6:12-46; 7:40-8:67; 13:22-14:17; 17:29-44; 20:12-40.<br>'470 patent at 3:24-50; *see also* 5:41-55; 6:16-50; 7:44-9:3; 13:20-14:20; 17:55-18:20; 20:52-67.<br>'527 patent at 3:24-50; *see also* 5:41-55; 6:16-50; 7:44-9:3; 13:24-14:17; 17:39-55; 20:10-39.<br>'106 patent at 3:31-57; *see also* 5:47-61; 6:21-55; 7:49-9:8; | *Substantially pure, optically active dextrorotary stereoisomer of medetomidine, as the free base*<br>**Citations to the '106 Patent:**[1]<br>"1. A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising ***dexmedetomidine or a pharmaceutically acceptable salt thereof*** disposed within a sealed glass container, wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of ***dexmedetomidine***." *See* '106 Patent at 26:19-25 (emphasis added).<br>"The present invention relates to patient-ready, premixed formulations of ***dexmedetomidine, or a pharmaceutically acceptable salt thereof***, that can |

[1] All four patents have substantively identical specifications, although the exact column and line citations may differ slightly between them. Here, representative citations to the '106 Patent are given as evidence of Defendant's proposed construction of the term "dexmedetomidine" in all of the asserted patents.

| | | | |
|---|---|---|---|
| | | 13:21-14:20; 17:57-18:25; 20:53-21:20. | be used, for example, in perioperative care of a patient or for sedation." *See* '106 Patent Abstract (emphasis added)..<br><br>"The present invention relates to premixed pharmaceutical compositions of ***dexmedetomidine, or a pharmaceutically acceptable salt thereof***, that are formulated for administration to a patient, without the need to reconstitute or dilute the composition prior to administration." *See* '106 Patent at 2:7-11(emphasis added).<br><br>"In certain non-limiting embodiments, the premixed dexmedetomidine composition is a liquid comprising ***dexmedetomidine, or a pharmaceutically acceptable salt thereof***, at a concentration of between about 0.05 µg/mL and about 15 µg/mL. *See* '106 Patent at 2:14-18(emphasis added).<br><br>"In certain non-limiting embodiments, the premixed dexmedetomidine composition of the present invention comprises ***dexmedetomidine, or a pharmaceutically acceptable salt thereof***, at a concentration of between about 0.05 µg/mL and about 15 µg/mL, and sodium chloride at a concentration of between about 0.01 and about 2.0 weight percent. In other non-limiting embodiments, the premixed dexmedetomidine composition of the present invention comprises d***exmedetomidine, or a pharmaceutically acceptable salt thereof***, at a concentration of about 4 µg/mL and sodium chloride at a concentration of about 0.9 weight percent" *See* '106 Patent at 2:33-42 (emphasis added). |

| | | | |
|---|---|---|---|
| | | | "In other non-limiting embodiments, ***dexmedetomidine*** comprises the structure depicted below in Formula I:<br>Formula I<br>  <br>*See* '106 Patent at 3:46-57 (emphasis added).<br><br>"In certain non-limiting embodiments, the premixed dexmedetomidine composition comprises dexmedetomidine, or a pharmaceutically acceptable salt thereof, at a concentration of between about…" *See* '106 Patent at 7:49-52.<br><br>"In certain non-limiting embodiments, the premixed dexmedetomidine composition comprises dexmedetomidine, or a pharmaceutically acceptable salt thereof, at a concentration of…" *See* '106 Patent at 7:64-67.<br><br>"In other non-limiting embodiments, the premixed dexmedetomidine composition of the present invention comprises dexmedetomidine, or a pharmaceutically acceptable salt thereof, at a concentration of about 4 µg/mL and sodium chloride at a concentration of about 0.90 weight percent." *See* '106 Patent at 8:63-67.<br><br>"The ***d-enantiomer of medetomidine, the generic*** |

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.