Paper No. _____ Date Filed: May 4, 2015

Filed on behalf of:

INO Therapeutics LLC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Praxair Distribution, Inc. Petitioner, v. INO Therapeutics LLC Patent Owner.

Case IPR2015-00524 U.S. Patent No. 8,293,284

PRELIMINARY RESPONSE BY PATENT OWNERS PURSUANT TO 37 C.F.R. § 42.107

> Mallinckrodt Hosp. Prods. IP Ltd. Exhibit 2019 Praxair Distrib., Inc. et al., v. Mallinckrodt Hosp. Prods. IP Ltd. Case IPR2016-00779

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TABLE OF AUTHORITIES

Cases

Apple, Inc. v. ITC, 725 F.3d 1356 (Fed. Cir. 2013)	4
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CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359 (Fed. Cir. 2002)2	1
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966)	5
<i>In re Cuozzo Speed Tech. LLC</i> , No. 14-1301, slip. op. (Fed. Cir. 2015)	1
<i>In re Dembiczak</i> , 175 F.3d 994 (Fed. Cir. 1999)2	,4
<i>Insite Vision Inc., et al. v. Sandoz, Inc.,</i> 2014-1065 (Fed. Cir. 2015)	.5
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	5
Leo Pharmaceutical Products, Ltd v. Rea, 726 F.3d 1346 (Fed. Cir. 2013)	3
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)2	1
<i>Rohm and Haas Co. v. Brotech Corp.</i> , 127 F.3d 1089 (Fed. Cir. 1997)4	.4
Statutes	
35 U.S.C. § 103	2
35 U.S.C. § 314(a)	2
35 U.S.C. § 325(d)4	6

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Regulations

37 C.F.R. § 42.1(b)
37 C.F.R. § 42.100(b)
37 C.F.R. § 42.104(b)(4)
37 C.F.R. § 42.108(c)
37 C.F.R. § 42.6
37 C.F.R. § 42.65(a)
P.T.A.B.
Int'l Securities Exchange, LLC v. Chicago Board Options Exchanges, Inc., IPR2014-00099, Paper 12 (P.T.A.B. May 22, 2014)
Integrated Global Concepts, Inc., v. Advanced Messaging Tech., Inc., IPR2014-01027, Paper 16 (P.T.A.B. Dec. 22, 2014)
Merial v. Virbac, IPR No. 2014-01279, Paper 13 (P.T.A.B. Jan. 22, 2015) 4, 25, 46, 48, 56
Mylan v. Gilead Sciences, Inc., IPR No. 2014-00888, Paper 15 (P.T.A.B. Dec. 9, 2014)4, 25
Mylan Pharma. Inc. v. Gilead Sciences, Inc., IPR No. 2014-00885, Paper 15 (P.T.A.B. Dec. 9, 2014)44
Zetec, Inc. v. Westinghouse Elec. Co., LLC, IPR No. 2014-00384, Paper 10 (P.T.A.B. Jul. 23, 2014)

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