

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A., et al.,	:	CIVIL ACTION NO. 11-3962 (MLC)
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
DR. REDDY'S LABORATORIES	:	
LTD., et al.,	:	
	:	
Defendants.	:	
	:	

OUTLINE OF SUPPLEMENTAL OPINION

PRELIMINARY STATEMENT	1
I. Findings of Fact	5
A. Medical treatment for emesis	5
B. The patents-in-suit	9
C. Factual chronology	11
1. Syntex and the genus '333 patent	12
2. Roche Syntex further development process	16
3. Helsinn license from Roche	23
4. The Oread agreements	30
5. FDA meeting March 10, 1999	33
6. Phase III protocol	40
7. Commencement of Phase III trials	49
8. The SP agreements	51
9. The MGI agreements	55
10. Status of Phase III clinical trials on January 30, 2002	62
11. Status as of patent application date, January 30, 2003	73
12. Issuance of patents-in-suit	78
13. Claim construction rulings regarding prosecution history	79
14. ANDA filings by Teva and others	81

II.	Conclusions of Law	82
A.	On-sale bar	82
	1. Legal standards and post-AIA statutory construction	83
	a. Historical analysis	83
	b. Parties' arguments regarding on-sale bar	86
	c. Interpreting the legal standard	87
	1. Statutory construction	87
	2. Agency guidelines	89
	3. Legislative history	90
	4. Public policy considerations	91
	d. Application of legal standards	92
	1. Statutory construction	92
	2. Agency guidelines	95
	3. Legislative history	96
	4. Public policy considerations	98
	2. Findings as to sale or offer to sell pre-AIA	100
	a. Applicable legal standards	101
	b. Parties' arguments	104
	c. Analysis	106
	3. Findings as to sale or offer to sell post-AIA	109
	a. Legal standard	109
	b. Parties' arguments	112
	c. Analysis	115
	4. Findings on ready for patenting	117
	a. Legal standards	117
	b. Applied legal standards	121
	1. Parties' arguments	122
	2. Expert opinions	123
	3. Analysis	141
	5. Conclusions as to on-sale bar claims	146
B.	Written Description	146
	1. Legal standards	146
	2. Findings and conclusions on written description	147
C.	Infringement	150
	1. Legal standards	150
	2. Findings and conclusions on infringement	154
	a. Parties' arguments	154

b.	Analysis	158
D.	Defining the Person of Ordinary Skill in the Art	161
1.	Expert testimony	162
2.	Analysis	163
CONCLUSION		165