UNITED STA	ATES PATENT AND TRADEMAR	K OFFICE
BEFORE TH	HE PATENT TRIAL AND APPEAL	BOARD
Т	WI PHARMACEUTICALS, INC. Petitioner,	
	v.	
_	MERCK SERONO SA Patent Owner.	
	Patent No. 8,377,903 Patent No. 7,713,947	
In	ter Partes Review IPR2023-00049	

DECLARATION OF BENJAMIN M. GREENBERG, M.D.



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В.	Ground 1: Claims 36, 38–39, 41–48 of the '947 Patent, and claims 17, 1 20, and 22–29 of the '903 Patent are unpatentable Under 35 U.S.C. § 10 as Anticipated by Bodor)2		
	1. Independent Claim 36 of the '947 Patent	50		
	a. Limitation 1: Preamble: "A method of treating multiple scleros comprising the oral administration of a formulation comprising cladribine following the sequential steps below:"	g		



	b.	Limitation 2: "an induction period lasting from about 2 months to about 4 months wherein said formulation is orally administered and wherein the total dose of cladribine reached at the end of the induction period is from about 1.7 mg/kg to about 3.5 mg/kg"51		
	c.	Limitation 3: "a cladribine-free period lasting from about 8 months to about 10 months, wherein no cladribine is administered"		
	d.	Limitation 4: "a maintenance period lasting from about 2 months to about 4 months, wherein said formulation is orally administered and wherein the total dose of cladribine reached at the end of the maintenance period is about 1.7 mg/kg;"57		
	e.	Limitation 5: "a cladribine-free period wherein no cladribine is administered"		
2.	_	Dependent Claim 38 of the '947 Patent: "method according to claim 6, wherein the induction period lasts about 2 months"65		
3.	Dependent Claim 39 of the '947 Patent: "method according to claim 36, wherein the total dose of cladribine reached at the end of the induction period is about 1.7 mg/kg"			
4.	-	Dependent Claim 41 of the '947 Patent: "method according to claim 36, wherein the cladribine-free period (ii) lasts about 10 months"66		
5.	Dependent Claim 42 of the '947 Patent: "method according to claim 36, wherein the cladribine-free (iv) period lasts 10 months			
6.	Dependent Claim 43 of the '947 Patent: "method according to claim 36, wherein the maintenance period lasts about 2 months"			
7.	Dependent Claim 44 of the '947 Patent: "method according to claim 36, wherein the formulation is orally administered at a daily dose of 3 to 30 mg cladribine"			
8.	Dependent Claim 45 of the '947 Patent: "method according to claim 36, wherein the formulation is orally administered at a daily dose of 10 mg cladribine"			
9.	36,	Dependent Claim 46 of the '947 Patent: "method according to claim 36, wherein the formulation is orally administered 1 to 7 days per month"		
10.	36,	wherein the steps (iii) to (iv) are repeated at least one or two es"		



11.	Dependent Claim 48 of the '947 Patent: "method according to claim 36, wherein the formulation is administered in combination with interferent beta".
12	Independent Claim 17 of the '903 Patent
	Dependent Claim 19 of the '903 Patent: "method according to claim 17, wherein the induction period lasts about 2 months"
14.	Dependent Claim 20 of the '903 Patent: "method according to claim 17, wherein the total dose of cladribine reached at the end of the induction period is about 1.7 mg/kg"
15.	Dependent Claim 22 of the '903 Patent: "method according to claim 17, wherein the cladribine-free period (ii) lasts about 10 months"79
16.	Dependent Claim 23 of the '903 Patent: "method according to claim 17, wherein the cladribine-free (iv) period lasts 10 months"
17.	Dependent Claim 24 of the '903 Patent: "method according to claim 17, wherein the maintenance period lasts about 2 months"80
18.	Dependent Claim 25 of the '903 Patent: "method according to claim 17, wherein the formulation is orally administered at a daily dose of 3 to 30mg"
19.	Dependent Claim 26 of the '903 Patent: "method according to claim 17, wherein the formulation is orally administered at a daily dose of 10mg cladribine"
20.	Dependent Claim 27 of the '903 Patent: "method according to claim 17, wherein the formulation is orally administered 1 to 7 days per month during the induction period"
21.	Dependent Claim 28 of the '903 Patent: "method according to claim 17, wherein the steps (iii) to (iv) are repeated at least one or two times"
22.	Dependent Claim 29 of the '903 Patent: "method according to claim 17, wherein the formulation is administered in combination with interferon-beta"
20,	und 2: Claims 36, 38–39, 41–48 of the '947 Patent and claims 17, 19–and 22–29 of the '903 Patent are Unpatentable Under 35 U.S.C. § 103 or Bodor
1.	It would have been obvious to administer a total dosage amount of



C.

	2.		rould have been obvious to repeat the same administration regimen rethe cladribine-free period
	3.	forn	rould have been obvious to use Bodor's oral cladribine dosage in and treatment regimen to treat relapsing-remitting and early ondary progressive multiple sclerosis90
D.	20,	and 2	3: Claims 36, 38–39, 41–48 of the '947 Patent and claims 17, 19–22–29 of the '903 Patent are Unpatentable Under 35 U.S.C. § over Bodor in view of Rice 200093
	1.	Inde	ependent Claim 36 of the '947 Patent95
		a.	Limitation 1: Preamble: "A method of treating multiple sclerosis comprising the oral administration of a formulation comprising cladribine following the sequential steps below:"95
		b.	Limitation 2: "an induction period lasting from about 2 months to about 4 months wherein said formulation is orally administered and wherein the total dose of cladribine reached at the end of the induction period is from about 1.7 mg/kg to about 3.5 mg/kg"95
		c.	Limitation 3: "a cladribine-free period lasting from about 8 months to about 10 months, wherein no cladribine is administered"
		d.	Limitation 4: "a maintenance period lasting from about 2 months to about 4 months, wherein said formulation is orally administered and wherein the total dose of cladribine reached at the end of the maintenance period is about 1.7 mg/kg;"102
		e.	Limitation 5: "a cladribine-free period wherein no cladribine is administered"
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	6.	_	pendent Claim 43 of the '947 Patent: "method according to claim wherein the maintenance period lasts about 2 months"



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