UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A. AND DR. REDDY'S LABORATORIES, INC.

Petitioners

v.

INDIVIOR UK LIMITED.

Patent Owner

U.S. PATENT No. 9,687,454

TITLE: SUBLINGUAL AND BUCCAL FILM COMPOSITIONS

Case No. IPR2019-00328

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,687,454

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Patent Trial and Appeal Board
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C.	Patent Owner Conceded That a POSA Would Have Had a Motivation to Formulate a Film Dosage Form That Was Bioequivalent to Suboxone® Tablets and Would Have Had a Reasonable Expectation of Success				
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	1.	Euro-Celtique discloses the preamble41			
	2.	Euro-Celtique discloses "about 40 wt % to about 60 wt % of a water-soluble polymer matrix" [1(a)]			
	3.	Euro-Celtique discloses "about 2mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof" [1(b)]			
	4.	Euro-Celtique discloses "about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof" [1(c)].			
	5.	Euro-Celtique and the Suboxone® PDR individually and in combination disclose "an acidic buffer" [1(d)]43			
	6.	Euro-Celtique teaches a film that is "mucoadhesive to the sublingual mucosa or the buccal mucosa" [1(e)]44			
	7.	Euro-Celtique and the Suboxone® PDR individually and in combination disclose a "weight ratio of [buprenorphine]:[naloxone] [of] about 4:1." [1(f)]45			
	8.	Euro-Celtique in combination with the FDA IIG database or alternatively routine experimentation discloses a "weight ratio of [buffer]:[buprenorphine] is from 2:1 to 1:5" (element 1(g)).			



	9.	Euro-Celtique in combination with the EMEA disclose the pharmacokinetic parameters in element 1(h)47		
E.	Dependent Claims 2-3 and 5-14			
	1.	Euro-Celtique in combination with the FDA IIG database or alternatively routine experimentation discloses a "weight ratio of [buffer]:[buprenorphine] is from 1:1 to 1:5" (claim 2)48		
	2.	Euro-Celtique in combination with the FDA IIG database or alternatively routine experimentation discloses a "weight ratio of [buffer]:[buprenorphine] is from 1.4:1 to 1:3" (claim 3)48		
	3.	Euro-Celtique in combination with Fuisz discloses a "weight ratio of [buprenorphine]:[polymer]of from 1:3 to 1:11.5" (claim 5)		
	4.	Euro-Celtique in combination with Fuisz discloses a "weight ratio of [buprenorphine]:[polymer][of] about 1:3." (claim 6) .51		
	5.	Euro-Celtique discloses a film comprising "about 48.2 wt % to about 58.6 wt % of the water-soluble polymeric matrix" (claim 7)		
	6.	Euro-Celtique discloses a film comprising "about 48.2 wt % of the water-soluble polymeric matrix" (claim 8)52		
	7.	Euro-Celtique discloses a film "wherein the water-soluble polymer matrix comprises a polyethylene oxide polymer alone or in combination with a hydrophilic cellulosic polymer" (claim 9)		
	8.	Euro-Celtique discloses a film "wherein the hydrophilic cellulosic polymer is hydroxypropyl cellulose, hydroxylpropylmethyl cellulose, or a combination thereof" (claim 10)		



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