UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MODERNA THERAPEUTICS, INC.,
Petitioner,

v.

PROTIVA BIOTHERAPEUTICS, INC.,
Patent Owner.

Case No. IPR2019-00554
Patent No. 8,058,069

PETITIONER'S CORRECTED OPPOSITION TO PATENT OWNER MOTION TO STRIKE

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Moderna's Reply appropriately addresses (1) questions that the Board raised in its Institution Decision (Paper 8 ("ID")) and (2) arguments Protiva put forth in its Response. *See* 37 C.F.R. §42.23(b) (reply "may…respond to arguments raised in…patent owner response"), Trial Practice Guide Update, 83 Fed. Reg. 29,989, 18 (Aug. 2018) ("TPG") (reply may "address issues discussed in the institution decision"). Unable to fill the holes in its responsive arguments, Protiva seeks to limit the record available for the Board's consideration. But, the issues that Protiva claims are "new" are nothing of the sort—the Board specifically acknowledged these very issues when instituting this proceeding.

While Protiva complains that the Reply goes beyond the Petition, "expan[sion] of the same argument made in [the] Petition" to address a Patent Owner's arguments is the purpose of a Reply. *See Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1381 (Fed. Cir. 2018). "[T]he Board is capable of identifying new issues or belatedly presented evidence when weighing the evidence at the close of trial … [thus] striking the entirety or a portion of a party's brief is an exceptional remedy that the Board expects will be granted rarely." TPG, 17-18. Protiva presents no basis to grant such an exceptional remedy here.

1. The Petition Raised Routine Optimization Arguments

The Board has already rejected Protiva's argument that the Petition did not raise routine optimization (Mot., 1- 2). *See* ID, 24-25, n.11. The Petition, *e.g.*, pointed to "testing relating to the 2:40 formulation that the Patent Owner

identified as a prior art formulation" as a starting point (Pet., 31; EX1008, ¶109) and argued, *e.g.*, that "determining the optimal proportion of cationic lipid for a given lipid combination would be a simple matter of varying the proportion using prior art methodologies" (Pet. 33; Ex. 1008, ¶112).

Protiva's argument that disclosure of a phospholipid range in the prior art is a "new" issue (Mot., 2) is similarly unfounded. The Board already determined that the Petition identified an overlapping phospholipid range and rejected Protiva's arguments to the contrary: "[t]urning first to Patent Owner's contention that neither the '196 PCT nor the '189 Publication discusses concentration ranges for phospholipids … we do not find this argument persuasive." ID, 23-24; *see also* Pet. 38-39 (citing 5-90% range for the non-cationic lipid (*e.g.*, the phospholipid) and noting that it must be adjusted when cholesterol (also a non-cationic lipid) is included), *see also id.*, 13, 24, 27 (citing 5-90% range). The Reply properly expands on these arguments.

Protiva's argument that the Petition included no motivation to include the four claimed lipid components (in particular a phospholipid and cholesterol) in carrier particles (Mot., 3) similarly ignores arguments from the Petition. As discussed above, the Petition identified prior art testing of the 2:40 SNALP formulation as a basis for its obviousness arguments and noted that "[t]his formulation includes 40% cationic lipid and 2% conjugated lipid, 10%

phospholipid and 48% cholesterol … [and had] [d]emonstrated efficacy *in vitro* and *in vivo*." Pet. 26; EX1008, ¶¶96, 109. The Petition further described that "[n]on-cationic 'helper' lipids, *e.g.*, certain phospholipids and/or cholesterols, can be combined with the cationic lipid to influence the ability of the particles to transfect cells." Pet., 8; EX1008, ¶63. These are thus not "new" issues.

2. Moderna's Rebuttal Of Evidence Of Non-Obviousness Is Proper

After Protiva offered evidence of non-obviousness in its preliminary response, the Board stated that Moderna should have "an opportunity to respond … [as] Patent Owner's evidence is better evaluated in the context of a completed trial where the record has been fully developed." ID, 27. The Reply points to glaring holes in Protiva's alleged evidence, including that patisiran, the alleged commercial embodiment, does not even use the claimed formulation. *See* EX1020, ¶¶139-141. The Board should reject Protiva's efforts to avoid Moderna's responsive arguments showing such inaccuracies.

Protiva's position that a Petitioner must guess what evidence of non-obviousness a patent owner may offer or be foreclosed from responding is untenable. Protiva's case support, *Praxair Distribution, Inc. v. Mallinckrodt Hospital Products*, IPR2016-00777, Paper 10, dealt with (1) serial IPRs regarding the same patent (*id.*, 2), (2) likelihood of success in the initial determination (*id.*, 9), and (3) the lack of analysis of non-obviousness evidence

from the original patent file wrapper (*id.*). Here, the Board already found a likelihood of success, this is the first IPR on the '069 patent, and the Petition addressed alleged unexpected results discussed in the file wrapper (Pet., 12-14).

3. Protiva's Mischaracterizations Of Dr. Janoff's Opinions

Moderna's original expert, Dr. Janoff, passed away in December 2019. Petitioner's new expert, Dr. Anchordoquy stated: "I may have emphasized different points or stated things differently, I agree with the general premises set-forth regarding the invalidity of the '069 patent as stated [by Dr. Janoff]" EX1020, ¶3. Protiva's argument that Moderna "abandons testimony of Dr. Janoff" (Mot., 5) is simply wrong. Moreover, Protiva had the opportunity to depose Dr. Anchordoquy on any alleged inconsistencies (EX2043) and could have presented any such inconsistencies to the Board in its sur-reply.

The Board should reject Protiva's mischaracterizations of Dr. Janoff's opinions to manufacture alleged inconsistencies. Protiva points to ambiguous testimony from the '435 IPR arguing that Dr. Janoff opined that the claims should be limited to SNALPs (Mot., 4-5), but in that proceeding he testified that the broad definition of a "lipid particle" from the specification should inform the meaning of "nucleic acid-lipid particle." EX2001, 200:4-201:9. In this proceeding, Dr. Janoff unambiguously agreed with the Board's prior refusal to limit the claims to SNALPs. EX1008, ¶88; EX1022, 10-13 (Board decision). Dr.

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