



IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN

ACUITAS THERAPEUTICS INC.

PLAINTIFF

AND

ARBUTUS BIOPHARMA CORPORATION

DEFENDANT

RESPONSE TO COUNTERCLAIM

Filed by: The Plaintiff, Acuitas Therapeutics Inc. (the "responding party")

PART 1: RESPONSE TO COUNTERCLAIM FACTS

DIVISION 1 – RESPONSE TO FACTS

- 1. The facts alleged in none of the paragraphs of Part 1 of the Counterclaim are admitted.
- 2. The facts alleged in paragraphs 1 and 2 of Part 1 of the Counterclaim are denied.
- 3. The facts alleged in none of the paragraphs of Part 1 of the Counterclaim are outside the knowledge of the responding party.

DIVISION 2 – RESPONDING PARTY'S VERSION OF FACTS

- 1. The responding party denies each and every allegation contained in the Counterclaim except as admitted herein.
- 2. The responding party repeats and relies on the facts set out in the Notice of Civil Claim.
- In response to paragraph 10 of the Response to Civil Claim (relied on in the Counterclaim), gene therapy is not as described by the Defendant; rather, it is the delivery of mRNA or DNA into cells to express a protein. In the case of therapeutic applications of gene therapy, the expressed protein would provide a pharmacological benefit.

- 4. In response to paragraph 11 of the Response to Civil Claim (relied on in the Counterclaim), the meaning of "target" is not as described by the Defendant; rather, the meaning is defined in the Cross License Agreement. Further, gene therapy targets may comprise entire coding regions of the gene or the entire gene.
- 5. In response to paragraph 24 of the Response to Civil Claim (relied on in the Counterclaim), on or about May 27, 2015, Acuitas provided Arbutus (then Tekmira Pharmaceuticals Corp.) a copy of the sublicense granted to Moderna (the "Moderna Sublicense"), in accordance with the terms of the Cross License Agreement.
- 6. The Moderna Sublicense specifically refers to the terms of a Development and Option Agreement entered into by Acuitas and Moderna.
- 7. The terms of the Moderna Sublicense provide that the sublicense is for a licensed target, in this case Influenza A, as opposed to a specific formulated product.
- 8. Further, the Moderna Sublicense expressly grants Moderna a sublicense to technology inlicensed to Acuitas, pursuant to the terms of the applicable in-license.
- 9. As such, as of May 2015, Arbutus was aware of Acuitas' work with Moderna under the Moderna Sublicense and the specific terms of the sublicense.
- 10. Arbutus has also benefitted from Acuitas' work with Moderna. In February 2016, Acuitas notified Arbutus that Acuitas had achieved a milestone under the Cross License Agreement in connection with its work with Moderna and paid Arbutus a milestone payment, as required by the Cross License Agreement. Arbutus has never returned this payment.
- 11. Until June 2016, at no time did Arbutus express concerns with respect to Acuitas' work with Moderna or the Moderna Sublicense.
- 12. In response to paragraph 25 of the Response to Civil Claim (relied on in the Counterclaim), at all times, Acuitas has abided by the terms of the Cross License Agreement. Specifically,
 - (a) Acuitas was never assisted by, nor did it collaborate with, Moderna using Arbutus' technology without a license; no rights are provided to Moderna to use Arbutus technology in the Development and Option Agreement unless and until a sublicense is entered into;

- (b) Acuitas did not grant a sublicense to Moderna before it had developed a Sublicensable Product;
- (c) The Cross License Agreement does not restrict sublicensing to a "specific formulated product", as alleged; rather, it permits Acuitas to grant Moderna a target license:
 - (i) Sublicensable Product is defined in the Cross License Agreement as

...a Supplemental Field Product that has been developed by Acuitas and for which Acuitas has shown (i) in the case of an Antisense product, a pharmacological effect of that product against the Target or (ii) in the case of a Gene Therapy product a pharmacological effect resulting from expression of the protein, in both cases in *in vivo* studies in a small animal species;

(ii) Target is defined in the Cross License Agreement as

...any of (a) a nucleic acid that encodes or is required for expression of a polypeptide (including without limitation messenger RNA and miRNA), together with all variants of such polypeptide; (b) the set of nucleic acids that encode a defined non-peptide entity, including a microorganism, virus, bacterium or a single cell parasite; provided that the entire genome of a microorganism, virus, bacterium, or single cell parasite shall be regarded as a single Target; or (c) naturally occurring interfering RNA or miRNA or a precursor thereof;

(iii) Section 3.1 of the Cross License Agreement provides:

For the purposes of section 3.1, a Supplemental Field Product shall be considered the same Supplemental Field Product provided that the intended Targets remain the same and, for greater certainty, any change of the lipid nanoparticle formulation or any other drug delivery particle, vehicle and/or mechanism or change in the Antisense or DNA plasmids or mRNA (the "Acuitas Payloads") or any chemical modification to the Acuitas Payloads, any change in dosages strength, an change in the sequence of the Acuitas Payloads for the intended Target, or any addition of or change in any other active pharmaceutical ingredients delivered with the Acuitas payloads, does NOT constitute a new Supplemental Field Product if the intended Target remains the same;

- (d) The Moderna Sublicense is for a vaccine; a vaccine is a Gene Therapy product as defined in the Cross License Agreement; and
- (e) The Moderna Sublicense otherwise complied with the definition of Supplemental Field Product.
- 13. In response to paragraph 27 of the Response to Civil Claim (relied on in the Counterclaim), the Cross License Agreement does not prohibit Acuitas from developing products jointly with third parties. Further, the licensing options granted to Moderna pursuant to the Development and Option Agreement were merely options, not sublicenses; no rights were granted to Moderna thereunder unless and until a sublicense was granted by Acuitas in accordance

with the Cross License Agreement. Accordingly, Acuitas was not required to test products over which those options were granted in a small animal species, or meet any other of the requirements of the Cross License Agreement.

- 14. In response to paragraph 28 of the Response to Civil Claim (relied on in the Counterclaim), Acuitas gave notice to Arbutus of a second sublicense entered into with Moderna, in accordance with the Cross License Agreement. Acuitas denies that it breached the Cross License Agreement in respect of the second sublicense and repeats and relies on the facts pleaded in paragraph 12 herein with respect to that sublicense.
- 15. In response to paragraph 29 of the Response to Civil Claim, Acuitas has not provided Arbutus' technology to other third parties in breach of its obligations under the Cross License Agreement or otherwise.

DIVISION 3 – ADDITIONAL FACTS

16. N/A

PART 2: RESPONSE TO RELIEF SOUGHT

- 17. The responding party consents to the granting of the relief sought in none of the paragraphs of Part 2 of the Counterclaim.
- 18. The responding party opposes the granting of relief sought in paragraph 3 of Part 2 of the Counterclaim.
- 19. The responding party takes no position on the granting of the relief sought in none of the paragraphs of Part 2 of the Counterclaim.

PART 3: LEGAL BASIS

- 20. The whole of the Counterclaim should be dismissed as there are no breaches of contract, no wrongful gains, and no damages suffered by the Defendant.
- 21. Acuitas has not breached its obligations under the Cross License Agreement, as alleged, or at all, and, in specific response to paragraph 4 of the Counterclaim:

- (a) the Cross License Agreement does not restrict sublicensing to a "specific formulated product", as opposed to a target;
- (b) the sublicenses granted by Acuitas are for products that are Supplemental Field Products, specifically, Gene Therapy products, as these terms are defined in the Cross License Agreement;
- (c) Acuitas is free to grant sublicensing options to third parties; the Cross License Agreement does not require Acuitas to demonstrate a pharmacological effect in a small animal study prior to granting a sublicensing *option*;
- (d) at no time did Acuitas grant *sublicenses* for Supplemental Field Products prior to demonstrating their pharmacological effects in a small animal study;
- (e) the sublicenses granted were for products that were developed by Acuitas;
- (f) Acuitas did not provide or sell Arbutus' technology to third parties independent of a Supplemental Field Product; and
- (g) Acuitas did not encourage or permit any third party to use Arbutus' technology without a license or a sublicense.
- 22. In the alternative, if the Defendant suffered any damages, which is denied, then the damages claimed are remote, not available at law, and the Defendant failed to mitigate the damages.
- 23. Further, and in the alternative, if Acuitas breached the Cross License Agreement, which is denied, then Acuitas is entitled to equitable relief and Arbutus is estopped from relying on its rights under the Cross License Agreement on the basis that its conduct, including its awareness of the terms of the Moderna Sublicense and its acceptance of milestone and other payments from Acuitas, encouraged Acuitas to believe that Arbutus did not intend to rely on its strict rights, which caused Acuitas to act to its prejudice.

Address for service of the responding party:

Address for service:

McCarthy Tétrault LLP

Barristers & Solicitors

Suite 2400, 745 Thurlow Street

Vancouver BC V6E 0C5

Attention:

Miranda Lam

Fax number for service (if any):

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mlam@mccarthy.ca

DATED: December 9, 2016

For Miranda Lam

Counsel for the Plaintiff

Rule 7-1 (1) of the Supreme Court Civil Rules states:

- 1. Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,
 - (a) prepare a list of documents in Form 22 that lists
 - all documents that are or have been in the party 's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and
 - (ii) all other documents to which the party intends to refer at trial, and
 - (b) serve the list on all parties of record.