

Complaint Report

There were no stage two rulings in the second quarter.

UPDATE

Subject – Stage Three Appeal of Ruling in Amgen Stage Two Complaint vs Merck Brenzys APS in Biotechnology Focus

An appeal hearing was held July 18, 2017. This is a verbatim report from the hearing.

“PAAB Appeal Amgen vs Merck Brenzys July 18, 2017

This Appeal Panel included Anne Tomalin, President, TPIreg Inc. (Chair); Lucie Dufour, Lawyer, Lucie Dufour Lawyer Inc; and Mike Cloutier, Founding Partner, Accelera Canada Inc. On July 18, 2017, the Panel heard arguments from Merck, Amgen and PAAB regarding an editorial that had appeared in Biotechnology Focus.

Individuals representing Merck included: Cindy Belanger (UT Avocats), Anne Mayrand, Director, Legal & Compliance and Philippe Dussault, Director, Biosimilars and Loss of Exclusivity Brands. Individuals representing Amgen included: Emily Sherkey (Torys), Andrew Bernstein (Torys) and Ryan Lennox, Director and Senior Counsel for Amgen. Ray Chepesiuk, Commissioner of PAAB, presented on behalf of that organization. Patrick Massad and John Greiss were also in attendance from PAAB.

The issues considered by the Panel included the following:

- Does the journal piece under discussion meet the bar of "paid advertising directed at Healthcare Professionals"?
- If so, does the journal piece meet the requirements of the PAAB Code?

In coming to its decision, the Panel was sensitive to the precedents that would be set in making its decision for the innovative pharmaceutical industry. The Panel was also sensitive to the spirit and intent of the Code, in its interpretation of the words used therein.

The Commissioner of PAAB determined that the journal piece was an Advertising Promotional System (APS), Health Canada also determined that the journal piece was "advertising" and Merck advised that they accepted Health Canada's decision that the journal piece was "advertising". Therefore, the Panel did not address the issue of whether the journal piece was advertising.

In determining whether the journal piece was an APS paid for by Merck and directed to Healthcare Professionals, the Panel determined that the editorial was directed to the audience of Biotechnology Focus, which includes the following Healthcare Professionals: practicing healthcare professionals involved in conducting clinical investigations, practicing healthcare professionals involved in making reimbursement decisions and practicing healthcare professionals involved in the biotechnology industry. The Panel struggled with whether the editorial was paid for by Merck, either directly or indirectly. In their final decision, the Panel concluded that the editorial was paid for directly and indirectly by Merck. Direct payments included the ads placed by Merck in the journal and indirect payment involved the emerging relationship that was developing between the company and Biotechnology Focus.

The Panel therefore determined that the editorial was paid for by Merck and directed towards Healthcare Professionals, among others. This APS required PAAB approval before use, as determined by PAAB and Amgen.

In coming to this decision, the Panel also decided to make the following recommendations to Industry, to PAAB and to Biotechnology Focus.

Recommendations for Industry

- Interviews to the media should be conducted under SOPs. The SOPs should be developed in consideration of the PAAB code. Those conducting such interviews should be clear in terms of the limits that should govern their comments for a specific product.
- Industry should review editorial pieces from the media to assure that rules required for advertising of Drugs in Canada are met.
- When the media use PAAB-approved material, industry should object to the use of this material unless it is used in its entirety as it was approved by PAAB. The "PAAB approval" should be removed from the use being done by the media.
- When complaints are raised regarding an APS such as the one under review in this case, the Industry shall proactively modify the APS or require the third party to modify the APS. If the third party does not agree to the modification, there will be a record at the company of the directive requesting modification.

Recommendations for the Media

- Editorials focused on one product should be avoided. More than one interview should be conducted, including individuals with varied points of view.
- Media should consider how an editorial piece will be considered by organizations at arm's length from the journal and shall keep in mind regulations and limitations related to drug advertising in Canada.

Recommendations for PAAB

- The requirement for an APS to be paid for by the company in the PAAB Code should be removed.
- The definition of healthcare professionals in the PAAB Code should be amended to expressly include those individuals involved in making decisions for reimbursement.
- The requirement for advertising to be intended to influence prescribing practices in the PAAB Code should be amended to expressly include also the intent to influence the dispensing practices of healthcare professionals."