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Strauss Herb Company
755 Fortune Drive
Kamloops, BC
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Attention: Peter Strauss & Ty Hahn

Re: Strauss Enterprises Ltd. v. Minister of Health

When we met on November 21, 2008, to discuss the Federal Court Decision, I said that I would outline some of the highlights in a letter.

History

Parliament regulates prescription drugs with specific regulations which prohibit the sale of a prescription drug to the public without a prescription. The list of prescription drugs is found in Schedule F of the Regulations.

There is general agreement that a manufacturer cannot take a substance specifically listed on Schedule F and add it to a natural health product ("NHP"). If this was done, the NHP would contain a prescription drug and would have to be sold by prescription. The ***Natural Health Product Regulations*** would not apply.

Where the disagreement arose, is that Health Canada went further. Health Canada holds that if a lab can take a plant, or an NHP and can extract from the plant or NHP a substance listed as a prescription drug, then the plant or NHP is a prescription drug and can only be sold to the public by prescription (assuming approval under the drug Regulations).

The Strauss Herb Company started the Federal Court Action to specifically contest Health Canada classifying yohimbe bark as a prescription drug because yohimbine can be extracted from it. As I recall the Strauss Herb Company had a couple of concerns. One was that the list of plant and animal sources used to make NHPs from which a lab can chemically extract a prescription substance is potentially long. Some of these that were identified by experts in these proceedings include:

- green tea;
- black tea;
- cocoa;
- gotu kola;
- garlic;
- oils (Dr. McCutcheon used the plural to indicate several oils)
- chocolate;
- coffee;

- celery;
- lettuce;
- bananas;
- oranges;
- lemons;
- wheat;
- oats;
- peas;
- soybeans;
- corn;
- carrots;
- potatoes;
- tomatoes;
- spinach.

This is not meant to be an exhaustive list. It is merely the examples given by the experts engaged in the proceedings. One of the difficulties voiced by the experts formed your second concern, that all of the plants from which prescription substances can be extracted have not been identified making it unclear what is a NHP and what is a prescription drug.

The experts also identified the following non-plant NHP ingredients as containing prescription drugs:

- eggs;
- milk;
- chicken;
- beef.

Finally, uracil is a prescription drug. Every plant and animal contains uracil which is the prime building block of RNA. If Health Canada wanted to drive a NHP containing plant or animal material from the market, the Health Canada lab should be able to extract uracil which would make the NHP subject to the prescription regulations.

The Section Creating the Mischief

The Regulations at issue are C.01.041(1) and (1.1). They read:

> C.01.041(1) In this section and sections C.01.041.1 to C.01.046, "Schedule F Drug" means a drug listed or described in Schedule F to these Regulations.
>
> C.01.041(1.1) Subject to sections C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F Drug unless
>
> (a) the sale is made pursuant to a verbal or written prescription received by the seller;

We argued that there is no confusion as to what is a Schedule F drug. The Regulation makes

it clear it "means a drug listed or described in Schedule F". When the Regulations go on to say you cannot sell a "substance containing", we said that "containing" means containing as an ingredient, not "containing" as in you can chemically extract it. When Parliament listed "uracil" as a prescription drug, it was not meaning to prohibit the sale of anything containing a plant or animal cell because all plant and animals "contain" uracil. Rather, Parliament did not want manufacturers to add uracil as an ingredient.

We also argued that the purpose of the specific list of prescription drugs is to give the drug industry certainty as to what is and what is not a prescription drug. With the very specific list that we had before the Court Decision, a manufacturer could look at the prescription drug list and know whether their product was a prescription drug or not. If prescription drugs are meant to mean drugs not listed or described as a prescription drug but from which a prescription drug can be extracted, there is no certainty. Many NHP manufacturers will not now know whether their products are NHPs or prescription drugs.

We had also pointed out to the Court that Parliament adds plants to the prescription drug list when Parliament wants plants to be available by prescription only. When determining the meaning of a regulation, a Court is obligated to look at the regulations in the context of the entire regulatory scheme. Rather than do this, the Court termed things like the specific listings of plants and plant extracts on the prescription drug list as "drafting anomalies". This came as a surprise as there was no evidence in the Court proceedings as to why there are specific plants and plant extracts on the prescription drug list. So for example, rather than accept that the plant Rauwolfia was deliberately added to the prescription drug list to ensure that it was only available by prescription, it was termed as a drafting anomaly. It is a curious drafting anomaly as Rauwolfia contains yohimbine, the same prescription substance that the Court found made yohimbe bark a prescription drug. Why would Rauwolfia be listed at all if the Court's approach is correct.

The prescription list also includes "centella asiatica extract and active principles thereof". Centella asiatica is gotu kola. If the Court Decision is correct, there can be no question that gotu kola "contains" gotu kola extract. It is not clear what is meant on the prescription list by the "active principles" of gotu kola extract. It probably applies to substances such as alkaloids found in gotu kola. With the Court Decision, no-one knows what plants this listing will cover. All we know is that once the active principles are identified, any plants from which one can be extracted is a prescription drug. The point of all of this is that we have gone from certainty where NHP manufacturers knew they could not add gotu kola extract as an ingredient, to not knowing what this listing means.

We had also pointed out to the Court that subsection 2(2) of the *Natural Health Product Regulations* made no sense with Health Canada's interpretation. This subsection had to be referring to the plant and plant extracts listed as prescription substances. If this was not the case, the subsection would be meaningless. It could not be referring to the chemicals on the prescription drug list, as the addition of those ingredients would take any product out of the NHP definition. Courts are always cautioned not to adopt an interpretation that would render part of the regulatory scheme meaningless or absurd. The Court did not deal with this.

On the point of absurdity, we also pointed out the absurdity of Health Canada's approach. Health Canada is presuming all NHPs from which you can chemically extract a prescription drug

as dangerous because prescription drugs are dangerous. At the same time, the identical substances can be sold as foods without any danger. For example, now all NHPs that contain tea or chocolate are prescription drugs and need to be removed from the market to protect us from dangerous prescription drugs. At the same time, we are allowed to safely consume tea and chocolate as foods. This can only be described as bizarre and surreal. Surely this is not what Parliament intended. We can all understand that specific chemicals or plants which Parliament listed as prescription drugs require a prescription. We have difficulty understanding how things we consume as foods and which are not listed as prescription drugs are to be considered to be prescription drugs simply because they are added to an NHP.

The Effect of the Decision the New Bioavailable Testing

During the Court case, the Court was fixated on why the Strauss Herb Company had not determined whether the yohimbine in the product was bioavailable. In the Court Decision the Court said:

> [26] Unless Strauss was in a position to show that yohimbine is not a bioavailable compound within Strauss Energy SIX (a position it does not maintain), it is of no legal significance that the yohimbine gets into that product through the introduction of the parent bark. Strauss Energy SIX is a substance which contains yohimbine and it is clearly caught by Regulation C.01.041.

Later the Court held:

> [38] Fourth, Strauss argues that Health Canada's approach to Schedule F leaves it and the natural health products industry in a quandary of not knowing what is a Schedule F drug. This argument has no merit. Strauss knew that Strauss Energy SIX contained a clinical amount of yohimbine as an active and bioavailable stimulant. **I have to assume that the members of the natural health products industry similarly know what active compounds are present in their products.** Any health product which contains a Schedule F drug, however it may get there, is potentially subject to compliance action under Regulation C.01.041.

You will recognize the factual error in that there was no evidence yohimbine is bioavailable from yohimbe bark, let alone from Strauss Energy SIX. Nor did Strauss concede it was bioavailable. However, that is not the point you need to grasp. What is significant is that the Court:

1. wanted the Strauss Herb Company, and obviously all NHP manufacturers to test for bioavailability of all active compounds and prescription drugs, and

2. the members of the natural health products industry are to know what active compounds are present in their products.

My expertise is not in the area of clinical testing of NHPs for the bioavailability of active compounds. I am presuming that this would involve running a statistically significant clinical trial that measured the level of active ingredients in the blood of persons after taking a NHP.

Such trials would have to be done on each batch of a product, as active compounds in different lots of plant and animal ingredients can vary significantly.

If such testing can actually be done for all active compounds in a product like Strauss Energy SIX which has seven plant ingredients, I would expect that the cost would be prohibitive.

This part of the Decision has serious ramifications for the NHP industry.

In my opinion this part of the Decision is flawed. As we unsuccessfully tried to explain to the Court concerning the Court's fixation on bioavailability, if a manufacturer was charged with selling a NHP without a prescription, it would be no answer to the charge to prove the prescription drug was not bioavailable. The section prohibiting the sale of a substance containing a prescription drug does not limit the prohibition to "bioavailability". The interpretation of the regulations need to be the same, whether in Federal Court for a Judicial Review, or in a Provincial Court facing charges.

Flawed or not, unless successfully appealed, the Decision stands as the law.

Whether to Appeal

The Decision was released on November 21, 2008. You have 30 days to file an appeal (December 22, 2008). Unfortunately, only the Strauss Herb Company has standing to appeal the Decision. I say unfortunately, because you have communicated that unless others in the industry step in to assist in funding an appeal, that you will not appeal. My understanding is that you wanted me to write this letter, so that you had something outlining the Decision for others in the industry. Because this Decision affects the entire industry, I hope that you are successful in seeking support.

When we met last week I indicated that I doubted that I could do any appeal. At this point I am too busy to take an appeal on. That said, I know a couple effective appeal counsel in Vancouver that could take the file. I could assist on a as needed basis to provide expertise on the regulatory scheme.

The bright spot about any appeal, is that the question is a pure question of law. The three judges hearing the issue on appeal can determine whether the Decision is correct or incorrect without worrying about having to give deference to the initial Decision. This is significant as it means the matter is argued again with three Judges instead of one.

Yours truly,

Shawn P. Buckley
Law Corporation