Date: 20081121

Docket: T-2206-05

Citation: 2008 FC 1305

Ottawa, Ontario, November 21, 2008

PRESENT: The Honourable Mr. Justice Barnes

BETWEEN:

STRAUSS ENTERPRISES LTD.
dba STRAUSS HERB COMPANY

Applicant

and

THE MINISTER OF HEALTH OF CANADA

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

[1] Strauss Enterprises Ltd. (Strauss) is a British Columbia company that produces and sells herbal natural health products. In this proceeding, Strauss challenges the validity of a decision by Health Canada to classify one of its products (Strauss Energy SIX) as a Schedule F drug under the Food and Drug Regulations, C.R.C., c. 870 (FDA Regulations). The significance of that classification is that the retail sale of Strauss Energy SIX must be supported by a doctor's prescription. Strauss argues that Strauss Energy SIX should be classified and regulated as a natural health product under the Natural Health Products Regulations, SOR/2003-196 (NHP Regulations). Such a classification would require a product license but no supporting prescription. Strauss argues

as well that Health Canada's decision was made in breach of its duty of fairness, in particular, because Strauss was not adequately consulted before the decision was made.

[2] The Minister contends that the classification decision for Strauss Energy SIX was legally correct and that no duty of fairness arises in this situation. In the alternative, the Minister says that Strauss was, at all times, dealt with fairly and, to the extent that fairness was required, it was met.

a. Background

[3] Until it was voluntarily withdrawn from the market, Strauss Energy SIX was represented and sold by Strauss as an energy stimulant. For a period of time the product was also promoted as an aphrodisiac. Strauss Energy SIX is a composition product in capsule form made from a number of plant sources including sarsaparilla root, yohimbe bark, damiano leaf, oregano, hyssop herb, mullein leaf and cayenne. It is the presence of yohimbe bark in this product that gives rise to the present dispute between the parties.

[4] Yohimbe bark comes from the African yohimbe tree. In Africa there is a long history of using yohimbe bark as a natural stimulant. It is now understood that it is the presence of the alkaloid "yohimbine" in yohimbe bark that provides the desired stimulating effect.

[5] Yohimbine has been a compound of concern for Health Canada since about 1984. It was around that time that "yohimbine and its salts" were added to Health Canada's list of drugs which require a prescription in support of a retail sale. The historical record indicates that the regulator

concluded that yohimbine "is not a suitable product for self-medication". At that time some of the identified physiological responses to yohimbine were increased blood pressure and heart rate and occasional central nervous system stimulation. Although the early records do not specifically mention yohimbe bark, they do refer to "yohimbine-containing products" as the focus of regulatory concern.

[6] In early 2003 Strauss was charged with the offence of unlawfully selling Strauss Energy SIX, being a drug described in Schedule F of the FDA Regulations without a prescription contrary to Regulation C.01.041 of the FDA Regulations and contrary to ss. 31(a) of the *Food and Drugs Act*, R.S.C., 1985, c. F-27 (*Food and Drugs Act*). Strauss was also charged with a related offence dealing with the adequacy of its product labelling. Both of the charges were ultimately stayed by the Crown on July 16, 2004.

[7] In 2005, Health Canada initiated compliance action against Strauss in connection with Strauss Energy SIX and one other Strauss product. The full details of the interactions between the parties concerning Health Canada's compliance demands are set out more fully below, in the context of Strauss' fairness argument. Suffice it to say that it was this compliance action that precipitated this application by Strauss challenging Health Canada's regulatory interpretation.

[8] Health Canada maintains that Strauss Energy SIX contains the Schedule F drug "yohimbine" thereby requiring a prescription for its retail sale. Strauss contends that Health Canada's interpretation of the relevant regulations is incorrect because Strauss Energy SIX contains

"yohimbe bark" which is not a substance referred to in Schedule F to the FDA Regulations. This is the interpretation issue which the Court is required to resolve.

[9] Strauss characterizes the decision by Health Canada to enforce its legal interpretation of Schedule F as a reclassification decision. Having sold Strauss Energy SIX for several years without any objection from Health Canada, Strauss argues that the 2005 compliance action represented a change in Health Canada's approach to the regulation of products of this type. Strauss says that Health Canada unfairly failed to give it effective notice of its change in approach to Schedule F substances thereby depriving it of a meaningful right of prior consultation.

II. Issues

[10] (a) Is Strauss Energy SIX a substance falling within FDA Regulation C.01.041 because it contains the Schedule F drug "yohimbine"?

(b) Did the Respondent breach a duty of fairness in connection with its compliance action against Strauss?

III. Analysis

(a) *The Regulatory Background*

[11] Under the *Food and Drugs Act*, Parliament has established the statutory foundation for regulating the manufacture, advertisement, sale, labelling, packaging, importation and distribution of foods, drugs, cosmetics and therapeutic devices in Canada.

[12] Most of the specific legislative standards and controls contemplated by the *Food and Drugs Act* are established by regulation. The authority of the Governor in Council (GIC) to make regulations is found in s. 30 of the *Food and Drugs Act*. Included in that authority is the power to prescribe standards of composition, strength, potency, purity, quality or other property for any article of food, drug, cosmetic or device. In the interest of public safety the GIC may also regulate the sale or conditions of sale of any food, drug, cosmetic or device. Under ss. 30(1)(m) of the *Food and Drugs Act* the GIC is authorized to add anything to any of the statutory schedules annexed to the Act or to the regulations.

[13] Section C.01.041 of the FDA Regulations deals with the retail sale of prescription drugs. That provision states in part:

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) Dans le présent article et les articles C.01.041.1 à C.01.046, «drogue de l'annexe F» désigne une drogue énumérée ou décrite à l'annexe F du présent règlement.
(1.1) Subject to sections C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F Drug unless	(1.1) Sous réserve des articles C.01.043 et C.01.046, il est interdit de vendre une substance contenant une drogue de l'annexe F, à moins que :
(a) the sale is made pursuant to a verbal or written prescription received by the seller; and	a) le vendeur n'ait reçu une ordonnance écrite ou verbale;
(b) where the prescription has been transferred to the seller under section	b) dans le cas où l'ordonnance lui est transférée selon l'article

C.01.041.1, the requirements of section C.01.041.2 have been complied with.	C.01.041.1, les exigences de l'article C.01.041.2 n'aient été respectées.
[Emphasis added]	[Je souligne]

[14] Schedule F to the FDA Regulations is a listing of several hundred compounds and their derivatives which require a prescription for retail sale. The Schedule also stipulates the dates when many of the compound listings were added or changed. Included on Schedule F is a listing for "yohimbine and its salts" but it contains no reference to yohimbe bark.

(b) ***Preliminary Issues, Evidence and the Positions of the Parties***

[15] The parties devoted considerable attention and resources addressing the issue of the relative safety of yohimbe bark and Strauss Energy SIX for human consumption. Certainly after the decision was made to take compliance action, Health Canada more closely examined the issue of product risk by carrying out a Health Hazard Assessment for Strauss Energy SIX; however both parties accept that that evidence is not relevant to the statutory interpretation issue which is at the heart of this dispute. It follows, of course, that Strauss' complaints about the competence and adequacy of Health Canada's product risk analysis are also irrelevant to the interpretation issue.

[16] Strauss and its experts do not dispute that yohimbe bark can have a stimulating effect which could pose a risk for certain populations (e.g. those with high blood pressure or with kidney or liver problems). Strauss contends, however, that yohimbe bark has been used for centuries with few, if

any, adverse consequences and that any health risks can be more appropriately managed by product warnings and under the licensing provisions of the NHP Regulations.

[17] In the end, though, both parties concede that Health Canada's decision was based on its single conclusion that Strauss Energy SIX is a substance which contains yohimbine. Health Canada does not assert that its compliance decision was based on evidence of a specific health risk presented by Strauss Energy SIX. Rather, the Minister says that by placing yohimbine on the list of Schedule F drugs a risk-based policy choice was made, the reasonableness of which cannot be judicially reviewed.

[18] For its part, Strauss concedes that its case could not succeed on the merits if yohimbe bark had been expressly listed on Schedule F of the FDA Regulations. However, in the absence of such a listing, it says that Schedule F has no application to Strauss Energy SIX.

[19] Strauss and its experts point out that yohimbe bark and yohimbine are different substances. This appears to be the foundation for the argument that the Schedule F reference to "yohimbine and its salts" was not intended to include yohimbe bark because yohimbine is an alkaloid extract from the bark. The argument is that if the GIC had intended to include the bark in Schedule F it would have done so expressly and the failure to do so indicates an intention not to regulate the bark as a Schedule F drug. In effect this is an argument for implied exclusion based on the premise that the omission of yohimbe bark from Schedule F was deliberate.

[20] One of the Strauss expert witnesses, Dr. Steven Dentali, was asked whether there is a difference between yohimbe bark and yohimbine. On that point his affidavit states:

> 7. I have been asked to provide an expert opinion on whether yohimbe bark is yohimbine. I am clearly of the opinion that yohimbe bark is not yohimbine. Indeed, this goes beyond mere opinion. It is a general scientific fact that yohimbe bark is not yohimbine.

[21] Dr. Dentali's accompanying report concludes with the observation that if yohimbe bark is included in Schedule F because yohimbine can be extracted from it, then tea and chocolate should also be regulated substances because they contain the Schedule F compounds theophyline and theobromine.

[22] Dr. Robert Jackman and Dr. Allison McCutcheon, two other expert witnesses for Strauss, have provided similar opinion evidence to that of Dr. Dentali. Dr. Jackman and Dr. McCutcheon also offer the common opinion that there are different species of the yohimbe tree some of which contain no yohimbine or only traces of it.

[23] The Minister does not dispute that yohimbe bark and yohimbine are different substances and willingly acknowledged that point as an incontrovertible scientific fact. It is the Minister's position that Strauss Energy SIX contains yohimbine and it does not matter whether that drug got there as a constituent of yohimbe bark or as a directly added ingredient.

(c) ***Discussion Regarding Statutory Interpretation***

[24] There is no dispute in this case that Strauss Energy SIX includes yohimbe bark or that the bark used by Strauss contains yohimbine. Indeed, it is the very presence of yohimbine in Strauss Energy SIX that gives rise, in part, to the desired stimulating effect of the product. In the result, the only issue of contention between the parties is whether Health Canada's legal interpretation of Regulation C.01.041 of the FDA Regulations was correct in law. Strauss did not attempt to challenge the decision on any other basis. It does not matter, therefore, whether Health Canada's interpretation constituted a change from an earlier view or whether Health Canada was for a time uncertain about the strength of its legal position. The essential question remains: was Health Canada's interpretation of Regulation C.01.041 legally correct? I agree with the parties that this question raises an issue of law for which the applicable standard of review is correctness.

[25] The fundamental problem with Strauss' argument is that it relies on a few drafting anomalies found among the several hundred compounds listed in Schedule F to support an argument for a strained interpretation of Regulation C.01.041. That provision is not at all ambiguous. It prohibits the retail over-the-counter sale of a substance containing a Schedule F drug. There can be no doubt that Strauss Energy SIX is a substance. In fact, it is a composition of several active compounds only one of which is powdered or granulated yohimbe bark. There is also no doubt and no dispute that Strauss Energy SIX contains yohimbine, albeit as a constituent of the bark.

[26] Unless Strauss was in a position to show that yohimbine is not a bioavailable compound within Strauss Energy SIX (a position which 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.

[27] Strauss argues that Regulation C.01.041 is only engaged when a Schedule F drug is an isolated or added ingredient in the formulation of the final therapeutic substance. Strauss says that Regulation C.01.041 would only apply if it was adding yohimbine or one of its salts to Strauss Energy SIX. This argument invites the Court to rewrite the Regulation to say, in effect, "no person shall sell a substance containing [as an ingredient] a Schedule F drug". There is no sound basis for the Court adopting such an interpretation and I decline to do so.

[28] In short, this is not an issue which is resolved by the language of Schedule F and Strauss mischaracterizes the problem when it says at para. 99 of its Memorandum of Fact and Law that "…either the Schedule F listing 'yohimbine and its salts' includes 'yohimbe bark' or it does not". The issue properly stated is whether Strauss Energy SIX is a substance which contains yohimbine thereby bringing it within the ambit of the Regulation. The interpretation issue, therefore, stands to be decided solely by the language of the Regulation C.01.041 and there I can identify no ambiguity.

[29] While I accept that the decision of the Supreme Court of Canada in *R. v. Dunn,* [1982] 2 S.C.R. 677, 44 N.R. 594, is not directly on point, the Court's analysis is, nevertheless, supportive of the Minister's statutory interpretation argument in this case. There the Court was concerned with a

charge of trafficking in psilocybin. Psilocybin is a free compound found in some types of mushrooms and it is listed in Schedule H to the *Food and Drugs Act* as a restricted drug. Eating mushrooms containing psilocybin produces a hallucinogenic effect. As in this case, the parent mushrooms were not listed in the statutory schedule and the accused argued, on the basis of a number of earlier authorities, that that omission provided a material defence to the charge. The Court characterized the positions of the parties in the following passage from its decision:

> The Crown's contention is that to follow the Parnell and Cartier cases would be to render the Food and Drugs Act nugatory in this connection. It does not rely upon the concept of trafficking by holding out a substance to be a restricted drug but argues that the words of the Act and Schedule H are broad enough in themselves to include as a restricted drug mushrooms containing in their natural state the specifically restricted drug Psilocybin. The position taken by the respondent is essentially to support the Parnell and Cartier cases and to stress the fact that mushrooms containing Psilocybin are not mentioned as such in Schedule H and, therefore, cannot be classified as a restricted drug.

The Court went on to hold that the reference to “psilocybin or any salt thereof” in Schedule H to the *Food and Drugs Act* was sufficient to bring within the ambit of the statute a natural plant product which contained that compound. The Court’s analysis of the statutory interpretation issue is set out in the following passage:

> In the face of the evidence given at trial and the concession made by counsel for the respondent that Psilocybin, not merely the constituents from which it could be made, existed in the mushrooms, it could not be said that there was not some evidence of trafficking in Psilocybin. The mushrooms contained the drug. There was evidence that the respondent knew it and that he assured his prospective purchasers that it was 'good stuff', that he invited them to try it, and that he had offered a pound for sale for $3,000, which would tend to exclude the possibility that the mushrooms were to be sold for their value as food. In my opinion, it is impossible to come to any other

conclusion than that there was evidence before the trial judge upon which a properly instructed trier of fact could have convicted the respondent of trafficking in Psilocybin and that the trial judge was in error in allowing the motion of no evidence.

While this disposes of the case at bar, it does not deal with the question raised by the cases of Parnell and Cartier. As indicated above, the case at bar was not seriously considered in the courts below on the merits because all the judges dealing with it considered that the Parnell case was decisive on the matter and that the considerations involved in the charge of trafficking did not differ from those involved in a possession charge. It will be apparent from what I have said that, in my opinion, the fact that Psilocybin may be contained within a mushroom does not destroy its character as a restricted drug under Schedule H of the Food and Drugs Act. It could therefore, in my view, be as much the subject of a conviction for possession as it could be for trafficking. If the Parnell case and the Cartier case go so far as to deny that proposition, then in my view, with the greatest respect for the learned judges involved in those decisions, I consider the cases were wrongly decided. I am not overlooking the absurdity argument which impressed the courts, but I would point out that what is prohibited with respect to possession is unlawful possession, not mere physical possession. To be unlawful there must be present a knowledge of the nature of the substance possessed. The farmer who unknowingly has 'magic mushrooms' growing on his land is not guilty of unlawful possession. It would seem to me that reason and common sense on the part of the authorities would protect him if on discovery of the nature of the mushrooms he took the necessary steps to have them destroyed. In any event we are not here concerned with a possession case. Our case is that of an accused charged with trafficking in Psilocybin in respect of whom evidence was placed before the trial judge that he had acquired the mushrooms, dried them, and offered to sell them at $3,000 a pound. As I have said above, there was evidence of trafficking before the learned judge and it was error to allow the motion of no evidence. I would therefore allow the Crown's appeal and remit the matter to the trial court for the completion of the trial.

[Emphasis added]

I am not convinced that there is any sound reason to depart from the above approach in the interpretation of Regulation C.01.041 and Schedule F to the FDA Regulations. There are legitimate public health concerns which arise from the sale of products which contain prescription drugs. The interpretation urged upon the Court by Strauss does not advance that public health interest because it would allow a product onto the retail over-the-counter market containing a drug which carries a potential health risk that the Minister has deemed to be unacceptable.

[30] Even if I was disposed to look for a legislative intention in the language of Schedule F, I do not think that it assists Strauss. What Strauss contends is that the GIC deliberately omitted a reference to yohimbe bark in Schedule F and intended thereby to exclude it from the application of Regulation C.01.041. Strauss' position as stated in its Memorandum of Fact and Law is as follows:

> If Parliament [*sic*] intended "Schedule F Drug" to include plants that are not listed or described on Schedule F but which contain substances that are listed on Schedule F, one would expect the definition to say this. The definition does not say this, and Parliament's[*sic*] listing of drugs on Schedule F makes it clear that Parliament [*sic*] draws a clear distinction between plants, plant alkaloids like yohimbine, and chemical substances.

Strauss' argument is in essence based on the implied exclusion rule of interpretation. In appropriate contexts that rule dictates that the legislature's failure to mention a thing is a basis for inferring that it was deliberately excluded: see Ruth Sullivan, *Sullivan and Driedger on the Construction of Statutes*, 4th ed. (Markham: Butterworths, 2002) at pp. 186-187.

[31] The implied exclusion rule is applied sparingly and with considerable caution. Some of the reasons for this were expressed by Newcombe J. in *Turgeon v. Dominion Bank*, [1930] S.C.R. 67, [1929] 4 D.L.R. 1028, at pp. 70-71:

> The maxim, *expressio unius est exclusio alterius*, enunciates a principle which has its application in the construction of statutes and written instruments, and no doubt it has its uses when it aids to discover the intention; but, as has been said, while it is often a valuable servant, it is a dangerous master to follow. Much depends upon the context. One has to realize that a general rule of interpretation is not always in the mind of a draughtsman; that accidents occur; that there may be inadvertence; that sometimes unnecessary expressions are introduced, ex *abundanti cautela*, by way of least resistance, to satisfy an insistent interest, without any thought of limiting the general provision; and so the axiom is held not to be of universal application.

I would add that in addition to the problem of drafting oversight is the problem of trying to discern an intention from the failure to say or to include something in a regulatory provision. These difficulties are particularly evident when the claimed omission concerns a regulatory or statutory schedule to which items are added or removed from time to time. In the drafting of substantive regulations particular attention would be expected to be paid to the use of consistent language, to the avoidance of redundancy and to the need for coherence; however, the addition of substances to an existing schedule by the GIC would be unlikely to receive such careful attention to contextual detail. Although a schedule to legislation is not subordinate text, it should not be readily resorted to as an interpretive aid and it should not be used in that way unless there is an ambiguity in the operative text of the legislation. Here, as I have said, I cannot identify any ambiguity in Regulation C.01.041. It is clear on its face and it catches the Strauss product.

[32] Even though Strauss stresses that a failure to list yohimbe bark on Schedule F is inconsistent with other Schedule F references to plant sources, there may be sound regulatory or scientific reasons for these situations and which would explain what might otherwise look like an inconsistent use of language. There is no way for the Court to know why a Schedule F reference was drafted as it was and, in any event, the possibility of redundancy cannot be ruled out.

[33] There is also at least one obvious reason why Schedule F does not refer to yohimbe bark. As Strauss and its experts have pointed out, not all species of the yohimbe tree contain yohimbine in their bark. An express reference to yohimbe bark in Schedule F would thus bring within the scope of Regulation C.01.041 some substances which have no reason to be there. By limiting the Schedule F reference to "yohimbine and its salts" the regulation catches only those substances which the GIC believed posed potential health risks.

[34] Strauss has raised a number of other points challenging Health Canada's interpretation of the *Food and Drugs Act* and associated regulations. I will deal with each in turn.

[35] First, I do not agree that Health Canada's approach to Strauss Energy SIX undermines the NHP Regulations or creates absurdities. There is no basis for concluding that Health Canada's application of Regulation C.01.041 to Strauss Energy SIX means that no regulatory room remains under the NHP Regulations.

[36] Second, to the extent that Strauss and its experts rely upon the presence of certain Schedule F drugs in food products, their argument is disingenuous. Foods are regulated separately from drugs under the *Food and Drugs Act* and Schedule F has no application to foods. Only where a food product is marketed for its therapeutic effects will it potentially fall within the regulatory scheme for drugs: see *Wrigley Canada v. Canada*, [2000] F.C.J. No. 607, 256 N.R. 387 (C.A.). The example given by Strauss at para. 90 of its Memorandum of Fact and Law of a doctor writing a prescription for chocolate (which contains the Schedule F drug theobromine) is, thus, not at all helpful to the interpretative analysis.

[37] Third, I do not find Strauss' argument about uracil at all compelling. This is a case about yohimbine and not uracil. There is nothing before me to establish that the Schedule F drug uracil is found in clinical amounts in plant or animal products or that it is in any way bioavailable in humans. I can only assume that Health Canada will approach each compliance situation with common sense and that it will not be inclined to enforce Regulation C.01.041 in a nonsensical way or in a way which wholly undermines the legislative scheme for regulating legitimate natural health products.

[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.

[39] And finally, for essentially the same reason as stated above, it is unnecessary for me to look to the NHP Regulations as an aid to the interpretation of FDA Regulation C.01.041. Substances containing Schedule F drugs are not regulated as natural health products: see ss. 2(2) of the NHP Regulations[1]. Indeed, the record discloses that Strauss' application for a natural health product licence for Strauss Energy SIX was refused on June 5, 2006 because the Natural Health Products Directorate of Health Canada concluded that the presence of yohimbine in Strauss Energy SIX excluded it as a natural health product.

1

2(2) For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the Food and Drug Regulations, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of those Regulations.	2(2) Pour l'application du présent règlement, n'est pas considéré comme un produit de santé naturel la substance, la combinaison de substances ou le remède traditionnel qui doit être vendu sur ordonnance selon le Règlement sur les aliments et drogues mais qui ne l'est pas conformément à l'article C.01.043 de ce règlement.

(d) ***Fairness - Background***

[40] Strauss argues that the Minister breached the duty of fairness in making the decision to "reclassify" its product as a Schedule F substance. In order to fully address that issue, it is important to understand the history of the dealings between Strauss and Health Canada leading up to the impugned decision.

[41] Health Canada took an active regulatory interest in Strauss in early 2005 following public complaints about Strauss' advertising. Kim Seeling, a Compliance Officer and Drug Inspector with Health Canada, was assigned to monitor a number of Strauss products including Strauss Energy SIX. In July of 2005, Ms. Seeling determined that Strauss Energy SIX capsules contained yohimbe bark. Later that year, she consulted the Natural Medicines Comprehensive database and learned that yohimbe bark contains the natural alkaloid yohimbine. On the strength of these findings, she wrote a "warning" letter to Strauss dated November 15, 2005 stating, in part:

> It has come to the attention of the Health Products and Food Branch Inspectorate (HPFBI) that Strauss Herb Company is advertising and selling the following products in contravention of the *Food and Drugs Act*, the *Food and Drug Regulations*, and the *Natural Health Products Regulations*:
>
> Strauss Energy SIX Capsules containing yohimbe bark
> Strauss Energy 6 Capsules containing yohimbe bark
> Strauss Healthy Cell containing chaparral leaf
> Strauss Lymphatic Capsules containing Chaparral leaf
>
> The following violations are noted:
>
> 1) Strauss Energy SIX Capsules & Energy 6 Capsules
>
> Therapeutic products that contain natural plant sources of Schedule F substances-and thus the Schedule F substances themselves-are required to be sold pursuant to a prescription. They are excluded

> from the *Nautral* [*sic*] *Health Products Regulations* (the NHPR) and are consequently drugs under the purview of the *Food and Drug Regulations* (the FDR) and its requirements.
>
> In Sections C.01.041.1 to C.01.046 of the FDR, "Schedule F Drug" means a drug listed or described in Schedule F to these Regulations. The *Strauss Energy SIX Capsules* and *Strauss Energy 6 Capsules* which are sold as therapeutic products with express claims "to improve sex life and energy" require prescriptions as they contain a drug containing a Schedule F substance, to wit: yohimbine, listed on Part I, Schedule F, to the FDR. As such and in accordance with Section C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F drug unless the sale is made pursuant to a verbal or written prescription received by the seller, etc."

[42] Ms. Seeling's letter went on to request Strauss' "voluntary compliance" to stop the sale of Strauss Energy SIX and to initiate a product recall. She requested a written response by November 22, 2005 and also invited Strauss to contact her if it had any questions or new information.

[43] On November 22, 2005 legal counsel for Strauss, Shawn Buckley, wrote to Ms. Seeling and challenged Health Canada's interpretation of the Schedule F reference to yohimbine and its salts. His letter stated this concern as follows:

> In your letter the heading "1) Strauss Energy SIX Capsules and Energy 6 Capsules" you write:
>
> > Therapeutic products that contain natural plant sources of Schedule F substances-and thus the Schedule F substances themselves-are required to be sold pursuant to a prescription. They are excluded from the *Natural Health Products Regulations* (the NHPR) and are consequently drugs under the purview of the *Food and Drug Regulations* (the FDR) and its requirements.

> In essence your letter is signalling a significant shift in the policy of your branch. Before natural plant sources of Schedule F substances were not considered to be Schedule F substances themselves. Now, if I understand your letter, natural plant sources of Schedule F substances are to be considered as Schedule F substances.
>
> I think that this new policy is wrong at law. I strongly suspect that if we had to settle this issue in court, a court would find that Schedule F is limited to the substances listed in it as opposed to plants from which Schedule F substances can be extracted. To find otherwise could lead to some absurd results, both concerning Schedule F and other schedules in federal legislation which would be open to the same interpretation.

[44] Mr. Buckley's letter went on to state that Strauss would not carry out a voluntary product recall for Strauss Energy SIX. Nothing was said about the continued sale of the product. Mr. Buckley concluded his letter by saying that he looked forward "to working with you on these issues to ensure that any concerns Health Canada has are dealt with in a fair and reasonable manner".

[45] In response to Mr. Buckley's letter and to some corresponding e-mail exchanges, Ms. Seeling wrote again to Strauss on November 28, 2005. Her letter addressed some issues raised by Mr. Buckley about the confidentiality of proprietary information and indicated that "we are willing to discuss the export of recalled products" to the country of origin. This letter reiterated Health Canada's position that Strauss Energy SIX was a Schedule F drug and Ms. Seeling sought confirmation that further sale of the product had been stopped. A written response was requested by November 30, 2005.

[46] On November 29, 2005, Mr. Buckley wrote to Ms. Seeling to confirm only that Strauss had stopped selling another product of concern but, once again, he offered no similar commitment with respect to Strauss Energy SIX. His letter concluded with the hope that a reasonable and fair resolution of the matter could be obtained.

[47] Nevertheless, on November 30, 2005 Mr. Buckley wrote to Ms. Seeling to indicate that Strauss would be commencing a legal proceeding to challenge Health Canada's Schedule F interpretation. His letter stated:

> Regarding the Strauss Energy SIX product, as you are aware, we disagree with the legality of the "new" policy. As a result, we will be starting a court process to seek:
>
> 1. a declaration that yohimbe bark is not a Schedule F substance;
> 2. an interim injunction against Health Canada taking compliance action until the issue is heard;
> 3. damages for any loss incurred by the Strauss Herb Company as a result of the new policy, and
> 4. costs.

[48] Ms. Seeling responded by letter dated December 5, 2005 as follows:

> Concerning Strauss Energy SIX and Strauss Energy 6, these products do not have market authorization in Canada. They are unapproved drugs. Furthermore, these drugs contain yohimbe bark, a natural source of yohimbine. Due to the presence of yohimbine in these products they are considered prescription drugs.
>
> Health Canada's position is that a drug containing a Schedule F substance, even if that substance is in a plant material, is a prescription drug. Drugs containing Schedule F substance are excluded from the *Natural Health Products Regulations* and are regulated by the *Food and Drug Regulations*.

> I am aware that you have taken the position of refusing to stop sale and initiate a voluntary recall of these prescription drugs. Accordingly, Health Canada will now consider further compliance options.

[49] Mr. Buckley responded to Ms. Seeling's threat of compliance action with a letter dated December 6, 2005 stating:

> There is a disagreement with Health Canada on the policy change to equate plants from which Schedule F substances can be extracted as Schedule F substances. I had advised Ms. Seeling in my November 30, 2005 letter, that we will be seeking the direction of the Court to settle the disagreement. Consequently, I was quite taken back to read Ms. Seeling's December 5, 2005 letter stating that "Accordingly, Health Canada will now consider further compliance options." It seems to me that it is Health Canada's interest to have this matter adjudicated by the Court in a timely manner. I am also concerned that Ms. Seeling is threatening compliance action when she knows that we are preparing to ask a Court for a interim injunction on any compliance action.

[50] This proceeding was commenced on December 15, 2005. The only subsequent compliance action taken by Health Canada was in the form of a Health Advisory issued on April 10, 2006 wherein consumers were advised not to use unapproved products containing yohimbine or yohimbe bark including Strauss Energy SIX capsules. The evidence indicates that, at some point, Strauss did stop the further sale of Strauss Energy SIX, albeit that no recall was ever carried out.

(e) ***Discussion Regarding Fairness***

[51] I have serious reservations about whether any duty of fairness can be said to apply to a decision like this one which involves only an issue of statutory interpretation. The federal

government is required on a daily basis to interpret and enforce the laws of Canada and not infrequently the interests of citizens or corporations will be adversely impacted by such decisions. Interested parties like Strauss can attack the legal correctness of the government's legal interpretations but I do not agree that the government must always give prior notice to or consult with such parties about the correctness of its legal interpretations before it acts upon them. The situation will be different, of course, where an administrative decision involves the exercise of a discretion or where the law is being applied administratively in a disputed factual context. That was the situation in *Canadian Pharmaceutical Technologies International Inc. v. Canada (Attorney General)*, [2006] FC 708, [2006] F.C.J. No. 906, where the decision under review contained a significant factual component and where the Minister failed to adequately ascertain the applicant's views or to explain the basis for the decision.

[52] Even if I am wrong about this, I can find no abrogation here of a duty of fairness. Ms. Seeling warned Strauss about Health Canada's legal position and about its intention to seek regulatory compliance. This was followed by a lengthy exchange of views covering several topics including the correctness of Health Canada's regulatory interpretation. Notwithstanding that dialogue both parties continued to disagree and Strauss brought this proceeding. No complaint was ever raised at the time by Strauss or by its legal counsel that Health Canada had acted unfairly or that Strauss needed more time to deal with Health Canada's apparent health concerns, to address the validity of its scientific assumptions or to modify Strauss Energy SIX to bring it into compliance. Strauss was well aware of the legal basis for Health Canada's decision and it was afforded the opportunity to express its own views. The parties continued to disagree and nothing further could

have been accomplished by extending the exchange of legal views. In fact, Mr. Buckley understood that an impasse had been reached and took the logical next step of bringing this proceeding to challenge Health Canada's position. Even at that nothing about Health Canada's decision concerning the Strauss Energy SIX product prevents other members of the industry or even Strauss from maintaining a dialogue with Health Canada about broader concerns that may arise from its legal interpretation. In short, Strauss was at all times treated fairly by Health Canada and Strauss' contrary arguments are unjustified. At the same time I can identify nothing about the conduct of Strauss that would support the Minister's argument that it is disentitled to relief on the basis of the principle of "unclean hands". If the Minister believed that Strauss' conduct posed a meaningful health risk it had other available avenues of legal recourse which it chose not to exercise.

IV. Conclusion

[53] I have concluded that Health Canada's decision under FDA Regulation C.01.041 to classify Strauss Energy SIX as a substance which contains yohimbine was correct in law. I also reject Strauss' contention that it was treated unfairly by Health Canada in making and in executing that decision. In the result, this application is dismissed. If the Crown is seeking costs against Strauss, I will receive its submissions in writing within the next 10 days. I will allow Strauss 7 days thereafter to file its response. Neither submission should exceed 5 pages in length.

JUDGMENT

THIS COURT ADJUDGES that this application is dismissed with the issue of costs to be reserved pending the receipt of further submissions from the parties.

" R. L. Barnes "
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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PLACE OF HEARING:	Vancouver, BC
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