Session: Substantive Constraints

Topic: Standard of Palpable and Overriding Error

Recommended time: 90 Minutes

Score: 100 Marks

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Facts

Sterling Health Biomedics Inc. (SHBI) appeals from the decision of the Federal Court that dismissed its application for judicial review.

The background facts are these: SHBI had applied to Health Canada seeking a licence for its new medical product, *Coroduin,* which is an oral herbal capsule formulation said to prevent the corona virus infection if ingested as prescribed. The company claims that the major ingredient of the product is derived from papaya leaves which inhibits the corona virus from latching its spiky surface proteins to the receptors of the healthy cells of the lungs in affected people and thereby reduces its ability to multiply.

After reviewing the application, the Minister of Health concluded that the evidence submitted by SHBI was insufficient to support the safe use of the product. The decision noted particularly that were the product to be approved, it would be classified and licensed under Natural Health Products (NHP) regulations which means that the product was to be available over the counter without prescription. However, the Minister observed that there is a risk of transient skin itching associated with the use of the drug and this could not be properly monitored if the product was sold over the counter.

At the Federal Court, SHBI argued that the Minister had misclassified its drug as coming under NHP regulations rather than under the Food and Drug Regulations. This is because *Coroduin,* though a herbal formulation, is a prescription drug which cannot be sold over the counter and should have been subject to regulations pursuant to the Food and Drug Regulations. SHBI believes that if the Minister had properly characterized the drug under the appropriate law, it

would have enjoyed the provisions under clauses 72 and 95 of the Food and Drug Regulations which states thus:

> 72
>
> (i) The Minister may not reject any application for license on the sole basis that the usage of such drugs has or may likely have side effect(s) on the users where such side effect(s) are not considered fatal or permanent.
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> (ii) In considering any application for license, the Minister shall seek submissions from the applicant as to any side effect(s) resulting from or to be encountered by users of the drug. Such submissions shall be reviewed by a panel of experts which shall make recommendations to the applicant on appropriate steps to be taken to address or reduce such side effects.
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> (iii) The Minister may refuse any application for license where, pursuant to (ii) above, the applicant has received any recommendation from the panel and has failed or neglected to observe or implement this within three months after such recommendation was made.
>
> 95. Any party aggrieved with the decision of the Minister in respect of an application for license may appeal to the Federal Court for judicial review.

The Federal Court had considered arguments from both parties and agreed that the Food and Drugs Regulations should have applied to this matter. However, the court concluded that the characterization of drugs is a factual exercise which is at the discretion of the Minister to decide. And having reviewed the Minister's decision, the court was of the view that it was reasonable and should be upheld.

On appeal, SHBI argues that the ruling of the Federal Court that reasonableness standard applies in this matter is erroneous. This according to the company is because the Minister's misclassification of the usage and side effect(s) of the drug is a matter of medical science analysis, and having adopted the wrong factual basis, it resulted in his error of misapplying the NHP Regulations to the facts of this case instead of the Food and Drugs Regulations. The company therefore asks for the ruling of the Federal Court to be set aside.

Question

You are on the panel of judges at the Federal Court of Appeal and SHBI's appeal has been assigned to you for the lead ruling. Both parties to the dispute have agreed that the correct

appellate standard applicable to this matter is that of palpable and overriding error because the issues involved are those of mixed fact and law and the error of law is inextricable from the facts. They seek your ruling on the application of this standard. Prepare a draft of your ruling, demonstrating how to apply this standard to the decision of the Federal Court.