

# 2010 HAROLD G. FOX MOOT

## MOOT PROBLEM

OCTOBER 16<sup>th</sup>, 2009

1. The following are reasons and judgment of the Trial Court of Canada, Intellectual Property Division. The decision of the Trial Court was subsequently overturned by the Court of Appeal; the reasons and judgment for which are also set out below.
2. Both Courts have jurisdiction over all issues raised in their respective decisions. The standard of review adopted by the Court of Appeal is also correct and not the subject of appeal.
3. The decision of the Court of Appeal is now appealed to the Supreme Moot Court for Intellectual Property Appeals.
4. All of the issues raised in the reasons given by the lower courts should be addressed by counsel for Seedy Enterprises Ltd. or The Dead Bull Group Inc. in their submissions. Arguments not referenced in the reasons of the lower courts may be advanced by counsel in their submissions, but only if they relate to the issues identified in the lower courts' decisions. The subject matter of the appeal is confined to the law of patents, but reference to the *Food and Drugs Act* (and *Food and Drug Regulations*) is acceptable in addressing the issue(s).
5. The formalities of the remedy sought, and costs, are not to be addressed.

**TRIAL COURT OF CANADA,**  
**INTELLECTUAL PROPERTY DIVISION**

**Date: 20090828**

**Docket: T-825-04**

**Citation: 2009 FCIP 150**

Ottawa, Ontario, this 28<sup>th</sup> day of August, 2009

**PRESENT: The Honourable Mr. Justice Strayned**

**BETWEEN:**

**SEEDY ENTERPRISES LTD.**

**Plaintiff**

**and**

**THE DEAD BULL GROUP INC.**

**Defendant**

Heard at Ottawa, Ontario, on May 1 – 29, June 1 – 30, July 1 - 27.

Judgment delivered at Ottawa, Ontario, on August 28<sup>th</sup>, 2009.

**REASONS FOR JUDGMENT**

**STRAYNED J.**

[1] This action is an action brought by the plaintiff, Seedy Enterprises Ltd. for judgment under s. 60 of the *Patent Act*, R.S.C. 1985, c. P-4 (the “*Patent Act*” or the “*Act*”) declaring Canadian Patent 6,456,007 (the ‘007 Patent) invalid and void.

[2] The ‘007 Patent is owned by the defendant, The Dead Bull Group Inc. (“Dead Bull”), and is entitled “Administration of a Tonic”. The ‘007 Patent describes benefits to human beings who consume an extract made from grapefruit seeds in accordance with instructions provided in the

patent. The '007 Patent teaches that the use of the extract will “increase alertness and mental acuity in the short term, despite pre-existing conditions of exhaustion or mental lassitude”.

[3] For the reasons set out below, I find that the '007 Patent is invalid because the subject-matter claimed is not patentable as it is a method of medical treatment.

[4] Dead Bull is the well-known European originator of the Dead Bull caffeinated confection, “Corrida de Toros”. Due to the raging success of Corrida de Toros, and other Dead Bull brand products in the Canadian market, Dead Bull set up a research facility in Pamplemousse, Quebec.

[5] In the late 1980s, a researcher at the Dead Bull research lab, Dr. Manuel Rodríguez Sánchez, began to investigate the effect of grapefruit seed extract on rats. The rats demonstrated increased metabolism and physical activity. When placed in a laboratory maze the rats would scurry through it in a frenzied race. It was Dr. Sánchez who coined the popular term “rat race”.

[6] Dr. Sánchez then began experimentation with human subjects in the 1990's. His results were, however, not as promising. This was largely due to Dead Bull's insistence that the grapefruit seed extract be added to Dead Bull's Corrida de Toros (as to produce a grapefruit version of the caffeinated confection). There was little quantifiable impact on metabolic (or muscle) activity when the combination drink was consumed. Undaunted, Dr. Sánchez diluted the grapefruit seed extract and administered this by itself (without being added to the Corrida de Toros) to a group of test subjects (primarily young professionals and students) in the late 1990's and similar effects were experienced by those subjects, to that of the rats. Various means of administration were tested and documented including oral doses, capsules, intravenous and other modes of entry into the human body.

[7] Thereafter, the researchers focussed most of their experimental work on isolating the effect(s) of the grapefruit seed extract. With little delay, Dr. Sánchez had determined that grapefruit seed extract in capsule form was the most efficient means of administering it. After more work, the advantages of taking two capsules at a spaced interval were observed.

[8] Dead Bull took action on two fronts. First, the company prepared and filed a Canadian patent application. Second, a Dead Bull Nutraceuticals division was created to market the grapefruit seed extract as a “nutraceutical”. The product, entitled “Dry Grapefruit Juice” was introduced to a large and willing market of Canadian students and young professionals through a series of

promotional events (like air races, ultimate curling championships and poker events), and was an immediate hit.

[9] The introduction of the Dry Grapefruit Juice nutraceutical product did not go unnoticed in the Canadian marketplace. Seedy Enterprises Ltd. (“Seedy”) had been, for many years, a nutraceutical leader. Most of its sales were derived from its flax seed extract product which was purportedly effective in reducing tooth decay. Seedy’s primary market was young adults and featured various slogans like “bringing flaxy back” and “flax don’t floss”. However, before attempting to enter the grapefruit seed extract niche, Seedy had discovered that Dead Bull’s ‘007 Patent had issued. The ‘007 Patent was applied for in 2001 and issued in 2003.

[10] Seedy brought this action in 2004 to impeach the ‘007 Patent. As counsel for Seedy stated at trial, the purpose of the action is to allow Seedy to compete with Dead Bull without fear of patent infringement.

[11] At the heart of this dispute is claim 1 of the ‘007 Patent. The entire claim reads:

“The use of grapefruit seed extract for improving mental acuity in humans by ingesting 20 mg of said extract twice daily at an interval of between 20 and 30 minutes.”

[12] The parties agree, as do their expert witnesses, that the subject-matter of this admirably brief claim is both novel and inventive. Before the work at Dead Bull’s laboratory, nobody had appreciated that taking the grapefruit seed extract as set out in the patent would provide any benefit. Despite the use of grapefruit seed extract in other ways, the idea of using the grapefruit seed extract as taught in the patent would not have been obvious to a notional skilled worker at the time of publication of the patent.

[13] The parties, however, disagree as to whether the subject-matter of the claim is patentable under the *Act*. Section 2 of the *Patent Act* defines an “invention” as “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter”. However, not all ‘inventions’ satisfy this statutory definition. This impeachment proceeding, which effectively seeks a declaration of invalidity, requires me to determine whether the invention is patentable under Canadian law, or not.

[14] For the reasons set out below, I agree with Seedy that claim 1 is invalid as being directed towards non-patentable subject-matter.

[15] Claim 1 is defined as a “use” claim. There is no dispute that a new use for an old product may be patentable (*Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536). Thus, although grapefruit seed extract has been used for many years in various contexts, the fact that the patent claim recites the use of the extract for a new purpose is not, for that reason, objectionable.

[16] However, the use for the extract as set out in claim 1 is not for a commercial endeavour (such as lubrication of book spines (see Canadian Patent No. 5,000,001)), but is for a use that changes the physiological state of human beings. The patent’s specification itself is unambiguous about this – “following the regimen of taking two 20 mg capsules approximately half an hour apart, subjects are brought from blurred mental states to sharper and more focussed states.”

[17] Furthermore, as can be readily observed, although claim 1 refers to the “use” of the grapefruit seed extract, the claim is analogous to a *method* in that the claim defines a specific manner of taking the grapefruit seed extract.

[18] I agree with the capable argument of Seedy’s counsel, Cunning Q.C., that claim 1 when considered in light of the ‘007 Patent as a whole, defines a method – a method of taking a particular substance to achieve a desired physiological change in the person taking the substance. Thus, claim 1 covers a method of medical treatment. The grapefruit seed extract meets the criteria of a medicinal product, and the claim therefore defines a way that the medicinal product is to be taken by patients.

[19] Much was made in argument by Dead Bull as to the purported line between pharmaceutical and nutraceutical products. Although Canadian law does differentiate between pharmaceuticals and nutraceuticals in certain legal and regulatory contexts, I do not perceive there to be any distinction from the point of view of the *Patent Act*. There are many patentable products that are treated differently in law (and regulation) from each other. One would hardly expect a new children’s toy and a terrorist’s weapon to be subject to the same set of regulations and laws, yet from the perspective of patent law there is no basis for differentiating between the two.

[20] As the Canadian jurisprudence has defined a clear prohibition against the patentability of all methods of medical treatment (see, for example, *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111), claim 1 of the '007 Patent is invalid. As all the other claims of the '007 Patent depend from claim 1, the patent is invalid in its entirety.

[21] Judgment and costs to the plaintiff accordingly.

**COURT OF APPEAL**

**Date: 20091013**

**Docket: A-375-08**

**Citation: 2009 FCA 232**

**Ottawa, Ontario, this 13<sup>th</sup> day of October, 2009**

**CORAM: BILL J.A.,  
ABLE J.A.,  
HOURS J.A.**

**BETWEEN:**

**THE DEAD BULL GROUP INC.**

**Appellant**

**and**

**SEEDY ENTERPRISES LTD.**

**Respondent**

Heard at Ottawa, Ontario, on October 1 – 6.

Judgment delivered at Ottawa, Ontario, on October 13<sup>th</sup>, 2009.

REASONS FOR JUDGMENT BY:

ABLE J.A.

CONCURRED BY:

HOURS J.A.

BILL J.A.

**REASONS FOR JUDGMENT**

**ABLE J.A.**

[1] What is an invention? This is the ‘subject-matter’ of this appeal.

[2] The starting point for an appeal such as this is section 2 of the *Patent Act*, R.S.C. 1985, c. P-4 (the “*Patent Act*”, or the “*Act*”). Section 2 defines an “invention” as:

“any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.”

[3] At first instance, Strayned, J. held that claim 1 of Canadian Patent 6,456,007 (the ‘007 Patent) was not an “invention” under the *Act*. Although the learned judge correctly identified that a new use for an old product is patentable under the *Act* (per *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536), he misdirected himself as to the remainder of his inquiry. With all due respect, the decision below must be overturned.

[4] There are three issues that require consideration in analyzing the patentability of claim 1 of the ‘007 Patent:

1. Is the so-called “nutraceutical” product of the ‘007 Patent properly considered a “medicine”?; and if so,
2. Does claim 1 of the ‘007 Patent define a method?; and even if so,
3. Does the *Patent Act* preclude patentability for methods of medical treatment?

As set out below, this Court finds that each of these questions should be answered in the negative.

[5] I turn first to the question of whether the claimed benefits that come from taking the grapefruit seed extract as described in the patent are medicinal in nature. For the reasons set out below, I conclude that the claimed extract may provide certain benefits after consumption, but that this is insufficient to render the extract a medicine.

[6] Although the discovery of the extract’s efficacy, by Dead Bull, was made in a scientific setting and was supported by clinical trials, this is not sufficient to render the subject-matter of the claims “medical”. The fact that the product was marketed without the need for approval under the *Food and Drug Regulations* (C.R.C., c. 870) as a drug is further evidence to support a finding that the product is not a medicine. Under section 2 of the *Food and Drugs Act* ( R.S., 1985, c. F-27 ) (the “*Food and Drugs Act*”) a “drug” includes

“any substance or mixture of substances manufactured, sold or represented for use in



- (a) the diagnosis, treatment, or mitigation of prevention of disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring correcting or modifying organic functions in human beings or animals...”

Neither of these definitions of “drug” in the subsections is satisfied by the substance that is described in the ‘007 Patent (namely, the use of the grapefruit seed extract in combating fatigue). For this first reason, I reject the conclusion of Strayned, J. that the grapefruit seed extract is, in the context of the ‘007 Patent, a medicine. There is no pathological condition that is addressed by the solution described in the invention. The “symptoms” of being tired or unfocussed is endemic to the human condition and must be considered a symptom of being in a normal state, and not a pathological condition. If there is no pathology being addressed, there is no medicinal action occurring. I therefore disagree with the lower Court’s finding.

[7] Second, claim 1 of the ‘007 Patent is not in the form of a “method” claim.

[8] The claim, as drafted, is to a *use* of the grapefruit seed extract, and not to a *method*. The role of the courts is to take a patent claim as drafted, and not re-write the claim based upon a judicial interpretation as to its “essence”. By its very wording, the ‘007 Patent claims a new use and not a method.

[9] Therefore, the learned judge committed an error of law in finding that claim 1 was invalid as being directed to a method of medical treatment. The claim does not cover a method but rather a new use for an old product. Furthermore, even if the claim were otherwise held to be directed at a method and not a new use, as I have concluded above, the claim does not relate to a medicine (but rather to a nutraceutical product).

[10] Therefore, I find that claim 1 does not claim a method, nor does it relate to a medical use (or method). The so-called prohibition against patenting methods of medical treatment does not apply; and the invention is not excluded from patentability on that ground.

[11] In addition, even if (as the learned judge below concluded) claim 1 were directed at a method of medical treatment, I do not read the *Patent Act* as precluding the patentability of such a claim. Chief Justice McLachlin and Justice Fish, writing for the majority in *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34 put it well at para. 94:

“Our task, however, is to interpret and apply the *Patent Act* as it stands, in accordance with settled principles. Under the present *Act*, an invention in the domain of agriculture is as deserving of protection as an invention in the domain of mechanical science. Where Parliament has not seen fit to distinguish between inventions... neither should the courts.”

[12] Therefore, since the current *Patent Act* does not itself contain any specific provision that bars the patentability of methods of medical treatment, it is not the role of the courts to re-write the *Act* or second guess Parliament’s will. Accordingly, the decision in *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111 must either be interpreted narrowly, or no longer considered good law.

[13] The extensive clinical trials carried out by Dead Bull, and the lengthy disclosure that is found in the ‘007 Patent, shows that this new use of the grapefruit seed extract has been extensively studied and is well-understood. There is clearly a benefit to the public in rewarding the work done by Dead Bull with the exclusive rights that a patent confers, in exchange for the public disclosure that the patent specification provides. The invention is patentable.

[14] For these reasons, I would allow the appeal.

“I agree.”

Stephen Bill J.A.

“I too agree.”

Mary-Louise Hours J.A.