III.2 Recap of Nov 24 lessons & issues

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Presented by

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Step 1a): Definition of existing knowledge at the outset

Northwest Hydraulics

- CRA position (all work SP)
  - "work described … refers to standard devices and processes, which are routinely used in similar design situations all over the world."
- Tax Court Position
  - "It was the innovative combination and alignment of [these] factors that makes this project unique."

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Author's commentary:

The Northwest Case illustrates how CRA officials may deny claims on the basis the project

- appears to be "routine engineering"
- without providing support for their position but
- identification of "variables" for experimentation
- provide adequate evidence for the TCC

- US / IRS directives – perhaps CRA can adopt?
  - Patent safe harbour
  - Rebuttal presumption
    - IRS must demonstrate within common knowledge if denied

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Step 2: Correlate experiments to technological uncertainties (hypotheses)

- CW Agencies
  - "The word **hypothesis** in this context is normally considered to mean a provisional concept which is not inconsistent with known facts and serves as a starting point for further investigation by which it may be proved or disproved objectively."
- Maritime Ontario Freight Lines
  - "A **hypothesis** is a tentative assumption or explanation to an unknown problem and, as a rule, this requirement is met by the existence of a logical plan devised to observe and resolve the hypothetical problem."

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Identifying “key variables” within “hypotheses”

- Northwest Hydraulics
  - “I do not think that conventional engineering would be adequate to deal with **the variables** and the uncertainties that were inherent in the major disruption and diversion of the flow of the river resulting from the construction”
  - Technological uncertainty is something that exists in the mind of the specialist such as the appellant, who identifies and articulates it and applies its methods to remove that uncertainty.”

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Additional definitions of “scientific hypotheses”

- From Wikipedia, the free encyclopedia
  - For a hypothesis to be a scientific hypothesis, the scientific method requires that one can test it.
  - Scientists generally base scientific hypotheses on previous observations that cannot satisfactorily be explained with the available scientific theories.
  - Normally hypotheses have the form of a mathematical model.
  - A working hypothesis is a provisionally accepted hypothesis proposed for further research.

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Author's commentary: Evidence hypotheses via "test matrix."

- This would require the researcher to:
  - Identify the key variables which he/she believes explain the performance
  - Benchmark variables vs. existing models to predict their interaction
  - Rank the variables in order of significance
  - Test the variables to further understand shortfall of the existing models

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TCC - Role of the “expert witness”

RIS Christie : role of the scientists in determining SR&ED eligibility

- “What constitutes scientific research for the purposes of the Act is either a question of law or a question of mixed law and fact to be determined by the Tax Court of Canada, not expert witnesses, as is too frequently assumed by counsel for both taxpayers and the Minister.

- An expert may assist the court in evaluating technical evidence and seek to persuade it that the research objective did or could not lead to a technological advancement. But, at the end of the day, the expert’s role is limited to providing the court with a set of prescription glasses through which technical information can be viewed before being analyzed and weighed by the trial judge.”

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Flavornet – Nov 24 SRED webcast

- Hypotheses vs. SR&ED Hypotheses
- Terminology used by CRA & now TCC
  - Accuracy
  - Insulting to client

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- CRA provided no evidence of Standard Practice
- Potential vs. desire to appeal ?

Excerpt from 2002 Cargil patent industry problems & examples

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soluble hydrophobic ingredients they have been typically incorporated in fat based foods such as margarine, spread, salad dressing, and mayonnaise. While this approach is a technical solution to formulating the ingredient, it is contradictory and confusing to cholesterol-conscious consumers who are trying to reduce the amount of fat in their diets.

The incorporation of free sterols into aqueous systems has been a challenge due to the hydrophobic nature of free sterols. The literature describes various methods of incorporating sterols into water by either chemical modification or mixing with various emulsifiers. Numerous practitioners have proposed solutions for aqueous formulation, however, many of these solutions have inherent problems of their own including: the cost of chemical modification, the ineffectiveness of the products, the cost and/or food safety concerns of mixing through the use of organic solvents, poor stability, subsequent flocculation, and poor textural or flavor properties. The present invention is directed toward a novel formulation of plant sterols which provides for their use in aqueous systems and overcomes many of the problems with alternative aqueous formulations. The present invention does not require any solvents or drying steps, uses only readily available food materials, and uses methods and

is 1 part sterol to about 0.06 to about 0.1 parts polysorbate.

6. The composition of claim 5 wherein the ratio of sterol to polysorbate is 1 part sterol to about 0.08 parts polysorbate.

7. The composition of claim 1 wherein the monoglyceride has a melting point greater than 25° C.

8. The composition of claim 1 wherein the monoglyceride has a melting point greater than 50° C.

9. The composition of claim 1 wherein the monoglyceride is comprised substantially of fully saturated C18 fatty acids.

10. The composition of claim 1 wherein the polysorbate is selected from the group consisting of polysorbate 60, polysorbate 65, and polysorbate 80; or mixtures thereof.

11. The composition of claim 1 wherein the polysorbate is polysorbate 60.

Client analysis of Cargil patent.pdf - Adobe Acrobat Pro
File Edit View Window Help

Standard Industry Practice vs Flavor.Net Hypothesis – Plant Sterol Dispersion

Standard – US patent 6623780 B1 filed March 26, 2002 for Cargill

Objective: disperse FDA approved claim amount of .65 g plant sterols in one serving of beverage taken twice daily.

Method – Cargill

Melt sterols with emulsifiers at 50 C, spray with rapid cooling into powder

Disperse powder into water at 80 C, cool to 50 C add orange juice concentrate, pasteurize and homogenize and hot fill into glass bottles

12 g of sterols were dispersed in 13,417 g of liquid = .09% sterols in beverage.

To get the FDA's .65 g per serving of plant sterols 25 oz. of orange juice would need be consumed twice per day or 50 oz. in total which is one large bottle.

Method - Flavor.Net Partial Hot Fill Pilot Plant

Our challenge was to disperse the FDA's .65 g of plant sterols in 2 oz. of beverage vs 25 oz. as in the

Our challenge was to disperse the FDA's .65 g of plant sterols in 2 oz. of beverage vs 25 oz. as in the industry standard patent. This would require dispersion of 1.14 % in the beverage vs .09 % as in the orange juice patent.

Method: Heat portion of required water to 50 C, high shear mix plant sterols with emulsifiers adding Nutraflora a nutraceutically enhanced fructooligosaccharide dietary fiber, maintain heat and continue shear mixing add other heart healthy nutraceuticals namely resveratrol, green tea extract, omega 3 as well as acids, sweeteners and flavour, pump hot slurry to mix tank containing balance of room water, continue pump mixing then fill into regular vs hot fill stable plastic bottles.

This method offers improvements over the industry standards as it eliminates producing a spray dried powder, allows a single step mixing/heating/cooling/filling of regular bottles resulting in energy and packaging savings while producing acceptable micro results. The dietary fiber emulsified the plant sterols better than orange juice concentrate. (See industry report on emulsifying power of fiber and info on our specialty fibre chosen for its additional health benefits including gut health)

Efforts to date have shown this method resulting in approximately 80 % of sterols dispersed.

Advancement: .80 g of sterols were dispersed with a 20 % sedimentation rate. Effectively this means the FDA's .65 g is dispersed in a 2 oz serving. (See July 5/10 lab test – 12% of 11.4 g = 1.65 g per 96.5 = .80 g in 56.8 = 2 oz.)Further testing is required to eliminate sedimentation. Energy and packaging cost savings

Judges position on Uncertainty

- [38] In developing its two-ounce beverage, the main issue that the appellant had was suspending the plant sterols, which are a fat-based substance, in a liquid. To resolve that issue, the appellant used a methodology and a technology that are well established in the food industry, namely high-shear mixing, mechanical pumping, by trying to heat the product at different temperatures and by utilizing emulsifiers that existed in the market.

CRA testimony without evidence

- [43] In her testimony, Ms. Hassanein stated that, at the time of her review of the appellant's project 705, there were multiple patents related to dispersing plant sterols in different products under different conditions.

- [44] For these reasons, I conclude that the appellant has not succeeded in discharging its burden of establishing technological uncertainty since it was using methods and techniques that were available in the industry.

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Hypotheses – evidence vs. cross examination

- Mr. Schmalz referred to the hypothesis as follows
- . . . There is an uncertainty, obviously, involved in how much of the plant sterols we can successfully suspend. And the hypothesis is attempting to resolve those technical uncertainties by testing the non standard practices of trying to incorporate that much sterols into a liquid. . .
- [49] Mr. Schmalz was clear in identifying the purpose of the appellant's project, but he could not explain the hypothesis that was formulated in order to arrive at the overall objective, namely, proving or disproving an assumption through further investigation.

Lifechoice – clinical trials

- Failed for lack of experimentation
- 248(1) allows “ experimentation or analysis.”
- Difference was cited in Hun Medipharma
- New ruling inconsistent with Act & prior rulings

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Novalia - question of theory

- Patented device
- PhD Music
- Challenged validity of science
- Lessons?

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Formadrain

- Advancements
  - Chemistry of plastic (PEng)
  - Mechanical Integration to mandrel (PEng) &
  - Proprietary Insertion process

  - How & why challenged?

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How to add “technology depth” to rulings

- Expert witnesses?
- Other judges with patent & IP backgrounds?
- Independent review committees?

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Patent

- Anticipation
  - *Bombardier Recreational Products Inc v Arctic Cat Inc*, 2017 FC 207
    - [M]erely viewing, without more, may not satisfy the "enabling" condition.
- Common General Knowledge
  - *Frac Shack Inc v AFD Petroleum Ltd*, 2017 FC 104
    - Distinct from what in patent law is regarded as public knowledge.
    - Common general knowledge will include patent specifications that are well known amongst those versed in the art, may include all patent specifications
    - Does not necessarily include scientific papers
    - Does not include what has only been written about and never, in fact, been used in a particular art.

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Cases from September 16, 2016 to March 2, 2017

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Patent

- Expert Opinion
  - *Bombardier Recreational Products Inc v Arctic Cat Inc*, 2017 FC 207
    - There is no rule of evidence or rule of the Court mandating that expert evidence must be excluded where the expert strays into the province of the Court by opining on the legal issues before the Court.
    - the Court is never bound by such opinion and remains solely responsible for determining the issues before it.
    - In a patent proceeding, expert testimony opining on the construction to be given to patent claims and whether infringement has occurred or not deserves such wariness and heightened scrutiny.

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Patent

- Non-infringing alternative
  - *Apotex Inc v ADIR*, 2017 FCA 23
    - for a defendant to show that in the hypothetical world it would have been able to obtain a non-infringing product, the defendant must establish that in the hypothetical world it would and could have obtained sufficient quantities of non-infringing product, and that it would and could have used the non-infringing product
    - To prove "could have", the defendant must demonstrate that it was possible for it to secure non-infringing product.
    - To prove "would have", the defendant must demonstrate "that events would transpire in such a way as to put them in that position"

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Tax court lessons & opportunities

CRA & TCC areas for improvement?

- Do CRA scientists need evidence?
- Evidence vs. expert witnesses?
- Judges – Patent/IP + Tax?
- Setting time vs. just dates
- Cost of transcripts (email vs hard copy)
- Online vs. in person
- Live broadcast?

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