2016-2017 HAROLD G. FOX MOOT

MOOT PROBLEM

OCTOBER 4th, 2016

1. The following are the 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. Please do **not** make arguments regarding the standard of review.

3. The decision of the Court of Appeal is now appealed to the Supreme Moot Court for Intellectual Property Appeals.

4. All the issues raised in the reasons given by the lower courts should be addressed by counsel for NA-Seal Inc. or Biosell Ltd. 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 specific issues identified in the lower courts' decisions.

5. Without limiting the above, please note that issues concerning infringement, prior art (obviousness and anticipation), breadth of the claims, utility, ambiguity, sufficiency of disclosure, remedies, costs and interest are **not** to be addressed.

TRIAL COURT OF CANADA,
INTELLECTUAL PROPERTY DIVISION

Date: 20160912
Docket: T-234-16
Citation: 2016 FCIP 122

Ottawa, Ontario, this 12th day of September, 2016

PRESENT: The Honourable Justice Brein

BETWEEN:

NA-SEAL INC.

Plaintiff

- and -

BIOSELL LTD.

Defendant

Heard at Ottawa, Ontario, on September 5 – 9, 2016.
Judgment delivered at Ottawa, Ontario, on September 12th, 2016.

REASONS FOR JUDGMENT AND JUDGMENT

Brein, J.

1. The Plaintiff, NA-Seal Inc. ("NA-Seal") seeks judgment holding that its competitor Biosell Ltd. ("Biosell") is liable for patent infringement. In its defence, Biosell alleges that the asserted patent is invalid for naming the wrong person as an inventor and because the subject-matter of the patent claims was made available to the public more than one year before the patent was filed.

2. The case before the Court was much simplified before it reached trial. Infringement was admitted and only the two validity issues referred to above were live issues at the trial. Questions of extent of liability were deferred until a later time.

3. NA-Seal brings this action against Biosell for infringement of its Canadian Patent No. 9,999,123 (the 123 Patent). The 123 Patent covers a method of producing an antibiotic

called vinylmycin. The named inventor of the 123 Patent is Dr. Rob Kreddit, President and CEO of NA-Seal.

4. It is important to note that the 123 Patent covers a way to make vinylmycin, and not the vinylmycin antibiotic itself. In fact, vinylmycin is a well-known antibiotic that has been used for many decades and any patent rights in the antibiotic itself have long since expired. However, although vinylmycin has been manufactured by many entities and is widely available across Canada, it was an expensive drug to make due to the manufacturing process that had been used to obtain the antibiotic.

5. The original method of making vinylmycin was in batches in small reaction vessels. Each reaction vessel was carefully rinsed with distilled water between batches, ensuring a clean vessel for each new batch. Although vinylmycin could be “grown” in the reaction vessel in small batches, attempts to scale up this process had not been successful. When the size of the vessels was increased, or the distilled water was not used to carefully clean the vessels, the production of the antibiotic was severely curtailed.

6. The story of the 123 Patent begins at an NA-Seal plant that was used to make vinylmycin using the traditional method. In 2010, NA-Seal had a summer internship program for ten undergraduate chemistry students. Interns would gain familiarity with standard procedures in the field and would carry out the usual mundane tasks associated with student intern work. The summer interns joined NA-Seal on a voluntary basis and there was no written contract between the students and NA-Seal.

7. The intern program at NA-Seal unfolded in an uneventful way during the summer of 2010 until the final week of the summer intern program. During that week Dr. Kreddit took the Friday off to go to his cottage. He left the summer intern Anne Ion with the task of rinsing some of the vinylmycin reaction vessels and starting the process to grow new batches of the antibiotic.

8. The evidence was that Ms. Ion was normally a reliable, if not very clever, worker. However, in her haste to get out of the lab on a Friday, Ms. Ion mistakenly used saline solution to rinse the reaction vessels. She otherwise completed the process to start the manufacture of the antibiotic correctly and then locked up the building for the night. The next day, Ms. Ion went back to the NA-Seal facility to check on the batch and realized that there was far more vinylmycin than there should have been. Becoming worried, Ms. Ion rinsed and prepared other, larger reaction vessels, and transferred the growing

cultures to them. Again, she rinsed with saline solution, not the distilled water that she should have used.

9. On Monday, Ms. Ion saw how much vinylmycin had been produced over the weekend and, as she recalled on the stand, told one of her co-workers that “this must be some kind of record.” However, it was the last day of her internship so she merely completed the process sheets to record what she had done and joined the other interns at the local pub to celebrate the end of the internship. She left behind a note: “Dr. Rob – In pub if you need to speak – Anne.”

10. In the meantime, on returning from his weekend off, Dr. Kreddit checked the lab and immediately noticed the increased vinylmycin production. He closely reviewed Anne Ion’s process sheets and realized that a saline solution had been used to rinse the reaction vessels. He quickly saw the potential for using this method to scale up the production of vinylmycin. The problem for Dr. Kreddit was that the NA-Seal facility did not have any available over-sized tanks. Fortunately, a lab technician at NA-Seal also worked part time as a tour guide at the nearby Eureka Brewing Co. He knew Eureka was not running at full capacity and he suggested using one of the empty fermentation tanks at the brewery to carry out some test runs.

11. After a visit to Eureka, Dr. Kreddit agreed that the fermentation tanks would work well for the scaled-up test runs. The testing took place between October 12 and 15, 2010 and was a great success. The results showed that the process could be scaled up to large-volume commercial levels. It also showed that the process was not dependent on the concentration of salt in the solution used to rinse the reaction vessel – in this case the fermentation tank at Eureka.

12. A few weeks later, on November 1, 2010, NA-Seal filed a patent application in the United States directed at the salt-rinse process, naming Dr. Kreddit as the sole inventor. On the advice of its own licensing executive, and to extend its rights as long as possible, NA-Seal then waited one full year, until November 1, 2011, to file the corresponding application in Canada. That application ultimately was granted on May 20, 2014 as the 123 Patent.

13. The parties have agreed that the 123 Patent claims in issue essentially recite the prior art method for making vinylmycin, “further comprising the step of providing a saline solution rinse to the reaction vessel before the batch initiation step.” The 123 Patent also

includes in the specification, but not in the claims, the statement that the method of the patent will permit the scaling up of vinylmycin production to oversized vessels to permit lower-cost manufacturing.

14. NA-Seal has both commercialized the vinylmycin itself and has licensed others. The end result has been a lower cost antibiotic that is available to more Canadians who need the drug. The days of vinylmycin being an expensive niche product are over and Canadians have benefitted from the work done by NA-Seal.

15. That is not the end of the story, however, as the Defendant BioSell has been selling a vinylmycin product in Canada without any licence from NA-Seal. In its promotional material, BioSell boasts of having affordable prices because of its “state of the art saline solution process” for making vinylmycin. It is this process that the NA-Seal says infringes the 123 Patent.

16. For its part, BioSell has admitted that its process infringes the 123 Patent. BioSell alleges, however, that the 123 Patent is invalid. The first allegation is that the 123 Patent is invalid for anticipation on the basis that the operations at Eureka between October 12 and 15, 2010 constitute a public disclosure of the invention more than 12 months before the Canadian filing date.

17. Biosell also alleges that the 123 Patent is void pursuant to s. 53(1) of the *Patent Act* on the basis of an untrue material allegation in the petition willfully made for the purpose of misleading. In particular, Biosell says that the true inventor is Anne Ion and not Dr. Kreddit and that the decision to name Dr. Kreddit only was not the result of inadvertence or mistake. Indeed, Biosell claims it was a deliberate and fraudulent attempt to misappropriate the invention.

18. I must reject these allegations.

19. First of all, the work done at Eureka in October 2010 was all experimental.

20. As has been stated: “[t]he law in Canada has long been established that experimental use in order to bring the invention to perfection, does not constitute public use” (*Bayer Inc. v. Apotex Inc.*, 2014 F.C. 436 at para. 119). I find the test runs to be a textbook case of experimentation. Dr. Kreddit was clearly running the fermentation tank to test out the method. Accordingly, any disclosure made during these experimental runs cannot be cited against the 123 Patent for anticipation.

21. Further, although it is true that the experimental work at Eureka – including the rinse step – was able to be seen by some members of the public, there is no evidence that any member of that public actually knew what was being done by Dr. Kreddit and his team. There was therefore no public disclosure. Although it was admitted by Dr. Kreddit on the witness stand that the daily Eureka Brewery public tour came past the fermentation tank, there was no evidence that any person on those tours knew anything about antibiotics. I also refer to the words, albeit in another context, of Lord Macnaghten: "Thirsty folk want beer, not explanations." Members of the tour were no doubt interested in drinking beer, not in learning about how to grow micro-organisms. Counsel for Biosell's strenuous arguments about the probative importance of the large bags of salt next to the tank, and the sign reading "Stand Clear: Vinylmycin Production", can safely be ignored.

22. The second issue before me is one of inventorship. I again reject the allegations made by BioSell. Dr. Kreddit was the one who appreciated that the step of adding salt to the rinse could give rise to a commercially valuable method. The result of that apercu was to allow Canadians to have access to vinylmycin at a much lower cost and to benefit the health of our citizens. Arguments that the intern was the sole and true inventor miss the mark. It is not for this Court to disparage the work of the eminent Dr. Kreddit in favour of a lowly intern who so easily abandoned the project when given a chance to socialize. The invention was made by Dr. Kreddit.

23. If I am wrong in this finding, the fact that Anne Ion was taken on by NA-Seal as a summer intern means that any invention made by her was properly owned by NA-Seal. If it had not been for NA-Seal's summer intern program there would have been no opportunity for Anne Ion to have anything to do with vinylmycin. Antiquated notions of master-servant relationships should not pertain to the modern reality of scientific enterprises. Under these circumstances, NA-Seal is the proper owner of the invention and is entitled to file the patent application, as the company did.

24. Accordingly, I adjudge the 123 Patent valid and infringed by Biosell. Issues of damages, costs and interest are to be subject of a separate determination, to be carried out in due course.

COURT OF APPEAL

Date: 20160930
Docket: T-234-16
Citation: 2016 FCA 336

Ottawa, Ontario, this 30th day of September, 2016

CORAM: **Shaker, J.A.,**
Grane, J.A.,
Lyck, J.A.

BETWEEN:

BIOSELL LTD.

Appellant

- and -

NA-SEAL INC.

Respondent

Heard at Ottawa, Ontario, on September 24th, 2016.
Judgment delivered at Ottawa, Ontario, on September 30th, 2016.

REASONS FOR JUDGMENT BY: Shaker, J.A.
CONCURRED BY: Grane, J.A.,
Lyck, J.A.

REASONS FOR JUDGMENT AND JUDGMENT

Shaker, J.A.

1. Regretfully, this Court must overturn the decision of the trial judge in 2016 FCIP 122. Although she is a seasoned trial judge, on each of the two issues that were adjudicated, the judge below erred and must be corrected.

2. Firstly, the trial judge erred in holding that the test runs at the Eureka Brewing Co. on October 12 to 15, 2010, did not amount to a public disclosure. Whether a skilled person did in fact see the patented process, and understand it, is neither here nor there. What matters is whether the disclosure was public and a skilled person *could* have seen the disclosure. As stated by Justice Rothstein (as he then was) in *Canwell Enviro-Industries Ltd. v Baker Petrolite Corp.* (2002), 17 CPR (4th) 478 (FCA): "[i]t is not necessary to demonstrate that a member of the public actually analysed the product that was sold."

3. The facts in evidence were that the fermentation tank at the Eureka Brewery was identified to the public as being for the production of vinylmycin, a salt rinse was used, and the salt was clearly identified. Each day a public tour went past the fermentation tank and the evidence was that the rinse step was sometimes seen by the tour. The invention was therefore made available to the public. NA-Seal waited to file its Canadian patent application so as to extend its monopoly rights. It waited too long. Now it must bear the consequences of that decision. The public disclosure of the process, available to any person skilled in the art who could have walked past, deprives NA-Seal of the right to assert monopoly rights to this new method.

4. The trial judge further erred in holding that all the test runs fall within the so-called "experimental use" exception. The evidence at trial makes it clear that Anne Ion had done the "experiment" to show that the saline solution rinse gave rise to a better growth of vinylmycin. The subsequent tests on October 12 to 15, 2010 were merely to optimize the commercial process and do not fall within the exception for experimental use.

5. Further, nowhere in Section 28.2 of the *Patent Act* is there reference to any "experimental" use exception. In my opinion, the so-called experimental use exception is outdated and ought to be reconsidered. There is no need for judges to make law to provide this exception for experiments. Indeed, I question its necessity entirely. Inventors can take precautions to avoid making public disclosures. If they "need" to experiment in public areas, they can nonetheless take steps to preserve an air of confidentiality, such as physical barriers like curtains, or non-disclosure agreements. The NA-Seal company took no such precautions during the week of October 12 to 15, 2010. Is this type of cavalier approach to public disclosure something the patent system should be rewarding?

6. For the reasons above, I conclude that the 123 Patent is invalid on the basis that the subject matter of the claims was disclosed more than one year before the Canadian filing date.

7. As for the second issue in this appeal, I find that on the evidence at trial the claimed process was invented by Anne Ion and not by Dr. Kreddit. Ms. Ion was solely responsible for the inventive step of adding salt to the rinse. Without her, there would be no new method for making vinylmycin. Ms. Ion put the saline solution into the reaction vessels. Dr. Kreddit was not even present for Ms. Ion's experiments. The subsequent work to scale up the invention was merely routine and did not contribute to the inventive concept. Dr. Kreddit and NA-Seal must have known this and therefore the filing of the application naming Dr. Kreddit alone as the inventor was wrong and cannot be countenanced.

8. As for the idea that the invention of Ms. Ion was somehow assigned to NA-Seal, this Court concludes that she was not hired "to invent" by NA-Seal. To import such a term into her employment contract (if it can be said that she was, in fact, an employee) is a step too far. We therefore cannot find a contractual relationship between Ms. Ion and the company that would provide NA-Seal with the ownership of the invention and we therefore conclude that NA-Seal is not the patentee of the 123 Patent.

9. For these reasons, we conclude that the 123 Patent is invalid pursuant to s. 53(1) of the *Patent Act*. For all the reasons set out above, NA-Seal is unable to claim exclusive rights to the new and useful process claimed in that patent.

10. The appeal, therefore, is allowed and the action for infringement against Biosell is dismissed.

"I agree."

Grane, J.A

"I too agree."

Lyck, J.A.