Welcome to the July edition of the International Associates Action Group Newsletter. We are still looking for contributors so please get in touch with me at david@gearhartlaw.com. If interested in becoming an editor or just want to get involved in our Action group please do let myself or Cristina Guerra know. See you next Month!

Yours,

David Postolski

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A Blow against Pirates on the Internet

A recent decision of the Federal Court of Appeal has interpreted the Copyright Act, in a way that protects the rights of copyright owners on the Internet.

The Facts

Voltage Pictures, LLC and other related companies are producers of movie films. They launched an action – a proposed reverse class action – against persons they say have downloaded their movies illegally. However, unless the plaintiffs can determine the identities of the persons they believe have infringed their copyrights, they cannot advance the action.

In 2012 the Copyright Act was amended to add a “notice and notice” system relating to providers of Internet services and others. This system was a compromise and less robust than the U.S. Notice and Takedown system. Under the system the owner of copyright may send a notice of claimed infringement to an Internet service provider. The provider on receipt of the notice from a claimant must:

a) as soon as feasible, forward the notice electronically to the person to whom the electronic location identified by the location data specified in the notice belongs and inform the claimant that it is forwarding the message; and
b) retain records that will allow the identity of the person to whom the electronic location belongs to be determined and to do so for six months from the date the notice is received.

This system does not directly provide for disclosing the information required to be recorded.

Using this system, the plaintiffs sought information identifying suspected infringers including John Doe #1, who was joined as a defendant on behalf of a class of respondents who had engaged in similar activities. Rogers Communications Inc. (“Rogers”) assembled the identifying information but said that they were not prepared to disclose it without an order of the court.

The new system does not provide for disclosure of identifying information and an application must be made to a court for an order authorizing the release of the information. Such orders are granted under the court’s jurisdiction to order equitable discovery and are referred to as Norwich orders. Such orders grant a plaintiff discovery prior to bringing an action against a person involved in the infringing actions of others, even if innocently, because such a person is under a duty to assist the plaintiff injured by those acts by giving full information by way of discovery and disclosure of the identity of the infringer.

In granting such orders courts balance the benefit to the applicant against the prejudice against the alleged wrongdoer in releasing the information. Factored into the equation are the nature of the information sought, the degree of confidentiality associated with the information and the degree in which the order curtails the use to which the information can be put. In addition, the courts can order that the person from whom discovery is sought be reasonably compensated for the expenses arising out of compliance with the order.

In this case a judge of the Federal Court granted an order requiring the information to be disclosed to the plaintiffs. Rogers was prepared to disclose it so long as it was paid a fee. The judge ordered that Rogers disclose the records but on condition that the plaintiffs pay the fee requested by Rogers for the work to assemble, verify and forward the identifying information to the plaintiffs to be billed at $100 per hour plus HST.
The Appeal

The plaintiffs appealed to the Federal Court. They alleged there were tens of thousands of suspected infringers whose identifying information could only be had at the same fee. They assert that Rogers fee, as approved by the court, set up a multi-million dollar barrier between them and the information necessary to continue with the action.

In interpreting the Act, the court said that the overall aim was to ensure that in the age of the Internet, the balance between legitimate access to works and a just reward for creators was maintained. The Internet must not become a collection of safe houses from which pirates with impunity can pilfer the products of others’ dedication, creativity and industry. If this was allowed to occur the incentive to create works would decline or the price of proper users to access works would increase. All the laudable aims of the Act – protecting creator’s and maker’s rights, fostering the fair dissemination of ideas and legitimate access to those ideas, promoting learning, advancing culture, encouraging innovation, competitiveness and investment and enhancing the economy, wealth and employment – would be nullified. The Act must be interpreted to allow copyright owners to protect and vindicate their rights as quickly, easily and efficiently as possible while ensuring fair treatment for all.

Overall, when considering obligations under the system, the internet service provider must maintain records in a manner and form that allows it to identify suspected infringers, to locate the relevant records, to identify the suspected infringers, to verify the identification work it has done (if necessary), to send the notices to the suspected infringers and the copyright owner, to translate the records (if necessary) into a form that allows them both to be disclosed promptly and to be used by copyright owners and later the courts to determine the identity of the suspected infringers, and, finally, to keep the records ready for prompt disclosure.

In addition, given the legislative history, no fees may be charged by a service provider for carrying out these statutory services. This interpretation is driven by a legislative choice that, at least for the time being, priority is given to the considerations of access to identifying information to allow copyright owners the ability to protect and vindicate their rights over the economic interest of service providers. This also follows the broader purposes of the Copyright Act.

The system was enacted against the backdrop of the Norwich order process which includes the act of disclosure. Disclosure is not regulated and the equitable jurisdiction in relation to Norwich orders continues to be in place.

When the court considered this aspect of the matter they said that typically the costs associated with a motion for a disclosure order, as far as a service provider is concerned, should be minimal.

With respect to the trial judge’s order a legal error had been made since under the notice and notice system no compensation could be ordered for the activities that relate to it and any expenses should be limited to the costs relating to disclosure. Since Rogers provided no evidence concerning the costs associated with disclosure this would typically be nominal.

As a result, the court allowed the appeal and given the positions taken by Rogers, denied them any legal costs and required Rogers to pay the plaintiffs the costs of the motion and the appeal. The court said that if Rogers and other internet service providers considered the level of compensation for the work was unfair, they should ask the Minister to pass a regulation setting fees.
Comment

While this decision deals with a relatively narrow issue it also deals with the rights of copyright owners in a broader sense. The decision is consistent with a number of earlier decisions directed at infringement. The comments are all the more poignant since the plaintiffs are not angels and have been accused of being copyright trolls.

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Plain Packaging – no smoke without fire

In 2016, the UK Government required all tobacco products to be sold in plain packaging, but allowed some time to exhaust existing products in the market place. That time has now expired so from May 2017 all cigarettes sold in the UK will be in plain packaging. Plain packaging for cigarettes was first introduced in Australia in 2012, and this has led to some interesting discussions about the repercussions for trade marks in this business.

What is plain packaging?

The picture is an example of what all packets of cigarettes will look like in the UK now – there are a variety of equally gruesome pictures available! The main elements are:

- The grey-green colour which is thought to be the ‘ugliest colour in the world’
- The health warning must cover at least 65% of the packaging
- The brand name must meet size criteria and be in a plain font
- The variant of the brand is positioned below and in smaller plain print
- There must be no references to descriptions of the product, eg ‘low tar’ or ‘organic’

There are other restrictions but these are not related to the branding so are not discussed here.

The political thinking behind the plain packaging is that it will make smoking less attractive, particularly to young people.

The main function of a trade mark is to differentiate the goods/services of one organization from those of others. Trade marks come in many varieties, not just words or logos. The get up and branding plays a big part in this. Trade marks facilitate consumer choice and provide an assurance as to source and quality. It is what we use to discuss products and recommend them to our friends, or to avoid repeating a bad experience.

Trade marks are the repository of the goodwill in a business, that is, they represent the value of the company. It is thought that about 85% of the value of the NIKE company lies in its trade mark. The same product sold without the NIKE mark(s) would not be able to realize the same price – consumers want the genuine article and are prepared to pay more for it - it is the branding which tells them that it is genuine. This also makes counterfeiting lucrative. A counterfeit without the branding is just another competitor!

A significant proportion of goods seized by EU customs authorities are cigarettes. Plain packaging could make it easier to copy packaging (and to use the same format just changing the brand/variant for other products), and will make it more difficult to identify the counterfeits, not just by the enforcers but also by the manufacturers themselves who have to confirm to Customs that the products seized are indeed counterfeits.

The trade mark profession has identified some of the potential problems which could arise as a result of plain packaging legislation, namely:
For consumers:
   This makes it harder to tell which manufacturer the product comes from
   It makes it harder to tell the difference between the different products offered by the same manufacturer
   It makes it more likely that a consumer will buy the wrong product by mistake
   It makes it harder to distinguish a counterfeit from the genuine article

For manufacturers:
   It makes it harder to add and earn consumer value from their products
   It will be more difficult to explain the differences between products (how can cigarette manufacturers indicate a ‘low tar’ product under the present regime?)
   It will discourage investment in the development of new products because these are more difficult to introduce to consumers, and therefore more difficult to get a return on that investment.
   It will reduce competitive advantage
   It will reduce the leverage of manufacturers to negotiate deals with retailers and wholesalers
   Because of the need for different packages for the UK and elsewhere, it will increase costs
   There will be a loss of rights for non-use of marks, not just trade mark registrations but also common law rights which can no longer be acquired and will diminish over time, in relation to logos and get up.

For the market:
   It will be much more difficult for new entrants to the market as the barrier to entry is that much higher
   This will reduce competition, stabilizing the markets for those already in play
   It will increase counterfeiting because the products are that much easier to copy

For the Government:
   Higher levels of counterfeiting will result in loss of excise duty and VAT
   And higher costs for identification of counterfeits and prevention of smuggling
   If the change results in fewer people smoking, this will also reduce tax revenue collected.

Is there a cause and effect here? Does pretty packaging really encourage people to take up smoking? Is the effect of plain packaging legislation significant enough to justify the loss of property rights in trade marks consequently experienced by tobacco manufacturers?

One final thought, in view of the ‘ugliness’ and off-putting pictures now on plain packaging, perhaps there is a new market for attractive cigarette boxes, so that the original packaging can be discarded as soon as possible after purchasing!

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3D Vision – virtual-reality reality

3DVISION

3DVision LTD submitted Israel trademark application no. 273325 for “3DVISION” on 25 March 2015. The mark covers Services of design, construction, building and designing websites; design and development services, namely, development services of technological solutions, software development services, web hosting services and content management services, visual communication design, graphic design services; graphic and architectural simulations design services using computer software; computer services, namely, design services and development services of three-dimensional movies, pictures, motion pictures with sound, audio and visual aids; Creative services, namely, design and development of computer software and consulting services related thereto; design of animated websites; design services of websites for marketing and advertising purposes; design services of graphic illustration services for others; design services of customized multimedia products for educational, marketing, training, demonstrational, presentation, architectural, engineering and development purposes; design services of multimedia products in the form of applications of computer graphics and website hosting services for the exchange of graphics, images, text, computer simulations, architectural simulations, marketing and promotional videos between the parties, all in class 42.

The trademark department considered the mark as indicating three-dimensional perception and lacking distinctiveness for the relevant goods and services. Since other service providers used the term as well, they refused it under Section 8(a) of the Israel Trademark Ordinance 1972, and also considered it as contravening section 11(10) as being descriptive. Although the mark was filed in a specific font, the Examiner considered the san serif font as not having the minimal styling to render the mark registerable.

Furthermore, the mark was considered confusingly similar to Israel trademark number 191734 for D-Vision in class 34, but that mark lapsed on 30 January 2017 due to non-payment of the renewal fee.

On 28 December 2015 the Applicant argued that the mark had acquired distinctiveness through usage and was associated exclusively with the Applicant and thus was registerable under Section 8b of the Ordinance. The Applicant argued that the mark has been in use for 13 years and the public was exposed to it in various media including via the Internet. The Applicant also noted that since 2003 they had been using the identical Internet domain (not stylized) and had similar pages and channels in various social media including Facebook and YouTube for over five years. This exposure, continued usage and marketing investment had resulted in the mark being well-known for virtual reality and animation in the real estate business [MF – Virtual Reality Reality?]. An affidavit by the CEO was submitted to support these claims.

The Applicant requested a hearing and this was held on 24 April 2017. THE CEO, Mr Gili Cohen described the services provided and argued that the services were identified with the company name 3D Vision and were not considered by the consumers as relating to three-dimensional vision.

DISCUSSION

Section 8 of the Trademark Ordinance 1972 states the basic conditions for registerability as follows:

(a) No mark is eligible for registration as a trade mark unless it is adapted to distinguish the goods of the proprietor of the mark from those of other persons (a mark so adapted being hereinafter referred to as a “distinctive mark”).
(b) In determining whether a trade mark is distinctive, the Registrar or the Court may, in the case of a trade mark in actual use, take into consideration the extent to which such use has rendered such trade mark in fact distinctive for goods in respect of which it is registered or intended to be registered.

Distinctive character exists where the mark enables the consumer to identify the source of the goods or services and to differentiate from similar goods and services available from competing suppliers. If the mark is used for different goods or services, the consumer will know that they are all available from the same source. See Seligsohn Trademark and Related Laws 1973, page 20.

Traditionally, marks are considered as being on a spectrum from imaginary marks via arbitrary, through indicative, descriptive to generic marks. (see Appeal 5792/99 Telecommunication and Jewish Religious Education Family (1997) LTD Magazine “Family” vs. SBS Advertising, Marketing and Sales Promotions LTD magazine “Good Family”, p.d. 55(3) 933 (2001), page 943.

Generic and descriptive marks are inherently non-distinctive. Generic marks cannot be registered as they cannot acquire distinctiveness. This is also largely true for descriptive marks that even after long-term usage should not be monopolized. See the 2673/04 Coffee to Go Marketing (1997) LTD bs. Israel Shaked, 15 April 2007, and the Supreme Court ruling 296/86 Phillip Morris Inc. vs. Tobacco Co. LTD p.d. 41(1) 485, 491-492 where the following is stated:

There are trade marks that the acquisition of distinctiveness will not help. There are marks that are so descriptive that it would be inappropriate to prevent the public to use such marks. See Supreme Court ruling 144/85 Kill Non-Ferous Metals LTD. vs. Commissioner of Patents and Trademarks 42(1) 309, page 315: “and even if they have acquired secondary meaning, even if proven, this will not help registration, since they lack substantive distinctiveness, and so should not be the basis of a monopoly that steals the right to use the term from the public. The reason is that non-distinctive marks should remain in the public domain.

Section 11(10) also limits the registerability of descriptive marks or those comprised from words used in the trade that have acquired descriptiveness through use:

A mark consisting of numerals, letters or words which are in common use in trade to distinguish or describe goods or classes of goods or which bear direct reference to their character or quality, unless the mark has a distinctive character within the meaning of section 8(b) or 9;

In this instance we are dealing with a mark comprising letters and a number whose combination has no meaning in simple English, but can be understood as the combination of two words 3D (meaning three-dimension) and VISION (meaning sight or prophetic insight). The services for which registration of the marks is sought are design, imaging and computer graphics for architecture such that the customer is shown a three-dimensional representation. As the CEO of the Applicant, Mr Gili Cohen, explained in the hearing, the Applicant’s intention was to hint at the creation of a vision (in the prophetic or at least forward-looking meaning) by 3D.

In this instance, even if the term describes an aspect of the service provided, the Deputy Commissioner is of the opinion that the combination is not so descriptive that it cannot acquire distinctiveness. Furthermore, the mark can be interpreted as both ‘seeing in three dimensions’ and as a ‘three dimensional vision’, and this duality creates an ambiguity that distances the marks from the services provided.

To the extent that a mark is closer to the generic-descriptive end of the spectrum and further from the random or imaginary end, the applicant has to provide greater proof of acquired distinctiveness. (see Appeal 3559/02 Toto Gold
The Deputy Commissioner Ms Bracha considers that the Applicant has shown that the mark has acquired distinctiveness. In addition to the continuous usage, the Applicant has shown investment in promoting the company in various media. The Applicant submitted letters from customers that even though were word for word identical, indicated that the customers were familiar with the mark. The Applicant also appended Internet-based activities under the mark since 20003, in appendices 2,3,4, and 5 and accountancy statements showing a significant level of services provided under the mark.

Consequently, the 273325 mark is allowable and may be registered twelve months from when the 191734 mark was cancelled.

COMMENT

I am unhappy considering 3DVISION as being able to acquire distinctiveness. In other words, I agree with the Examiner and not with the Deputy Commissioner.

The Applicant may indeed by using the word vision in the meaning of Isaiah’s Vision, but it also means sight. A conventional computer screen is two-dimensional and can only show a two dimensional representation. By using shadows and vanishing points, the illusion of depth is created. Thus giving the customer the feeling of touring an apartment is actually a 3D vision. In other words, the phrase is descriptive, even though the term vision is alleged to be ambiguous.

There are many words that are ambiguous. Ultimately if one dictionary definition is generic for the goods or services provided, it should be considered generic, even if the same word has other uses. Thus one would not allow the word orange to be a brand of citrus fruit, even if the citrus fruit in question is green. A mobile phone company calling itself orange is another matter.

It is a little like awarding a trademark for VIRTUAL REALITY for the same services. Sure there is a pun and it is clever, but the term can be read as virtual reality as used in games and other applications, or as reality (real estate) that is virtual. Either way, the term is generic.

I am less than impressed with Applicant submitted letters from customers that are word for word identical. To me, this indicates that Applicant’s lawyer dictated them.

Nevertheless, I also note that although one might argue that WORD is generic and EXCEL is laudatory, both are identified with Microsoft via massive usage. It is possible that for virtual reality reality services 3DIVISION is indeed a well-known service provider and others are not using the term 3D vision, etc. Allowing the mark to publish for opposition purposes does give competitors a chance to submit proof of competing usage or that the mark is generic. Furthermore, even if granted, a trademark of this nature is always subject to cancellation proceedings, so if it is asserted against competitors using the term 3D vision in a generic manner, the mark may be cancelled.

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The Characteristics of an Effective Brand Name

Ideally, a proposed brand name should have the following characteristics:

(a) Brevity. Be simple and easy to understand. Long brand names, at least the ones that survive, tend to be simplified by consumers, for example COCA COLA becomes COKE.

(b) Easily remembered. Consumers have limited time and energy to devote to brand names. They are faced with a multitude of product choices. It is advantageous to choose a brand which is memorable and distinctive.

(c) Easily readable and pronounceable. As more markets are considered and additional linguistic and cultural issues arise the more difficult it will be to achieve this characteristic. Care must be taken to avoid unintended connotations. For example, PUFFS brand tissues may be acceptable in North America, but PUFF in German is a colloquial term for whorehouse and in England it sounds similar to "poof", a derogatory term for a homosexual. It has been suggested that words and brand names that start with a plosive (b, c, d, g, k, p, and t) convey power, speed or dominance. KODAK® and PONTIAC® are examples.

(d) Be meaningful. A name should communicate positive product attributes and avoid unpleasant connotations. Brands names such as LEAN CUISINE or DIE HARD are good examples. If the product or service is sold through imagery the brand name should encourage emotional bonding or be inspirational. The brand name should help position the product or service.

(e) Allow for some flexibility. If possible, a brand name should allow for adaptation to changing market needs. For example, Anderson Consulting changed its name to ACCENTURE to communicate the emphasis it placed on the future and BOSTON CHICKEN changed its name to BOSTON MARKET to reflect a shift to family meals. These changes allowed for more flexibility of the brand. LASTMINUTE.COM for travel services may be too limiting.

(f) Be suggestive of the product class. It may advantageous to choose a brand name which suggests the attributes of the class of product in issue. Frequently, this type of brand name is easy to recall, for example, TICKETRON for use in association with vending tickets for sports and entertainment events. However, if such a mark is descriptive it may be difficult to protect. In addition, it may be difficult to expand such a mark into other product categories.

(g) Work with a symbol or slogan. It is advantageous if a brand name works well with a symbol or slogan. For example, the trade mark APPLE has been widely used in association with computers and computer software together with a stylized representation of an apple.

(h) The proposed name must be legally available and registrable in the countries in which it is proposed to be used. Consideration must also be given to the availability of domain names which include the brand name or a substantial part of it. In addition, the mark should be legally strong, for example, marks that are descriptive or common to the trade, even if protectable, will only be entitled to limited protection.

(i) The proposed name should also be protectable under the Trademarks Act and registrable. For example, a descriptive mark may be difficult to register and to protect.

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A useful clarification of the “utility” requirement under Canadian patent law will affect both patent applications pending in the Canadian Patent Office, as well as issued patents in the course of litigation. In AstraZeneca Canada Inc. v. Apotex Inc., the Supreme Court of Canada considered the validity of a patent that claimed AstraZeneca’s drug esomeprazole, marketed in Canada under the registered trademark, NEXIUM. The patent claimed the optically pure salts of esomeprazole, a proton pump inhibitor used in the reduction of gastric acid, reflux esophagitis and related maladies.

The Canadian 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.” Section 27(8) of the Act provides that a patent cannot be granted for a mere scientific principle or abstract theorem. Rather the invention must be useful.

The “utility” requirement raises the question of just how useful the invention has to be. Over the last decade, the Federal Courts have been answering that question using the so-called “Promise Doctrine.” Although the doctrine has taken on a variety of different forms over the years, at its most extreme it stands for the proposition that any statement made in the specification is a “promise” that must be met by the time of filing (either through demonstration or sound prediction) in order for the patent to fulfill the utility requirement. In the world of pharmaceutical patents, where the specification often talks about treating various diseases, but patents are often filed based on promising in vitro data, the doctrine has led to a tug-of-war over promise between brand and generic manufacturers, with generic manufacturers seeking (and often succeeding) to raise the bar on promise so as to invalidate the patent. However, in its unanimous decision the Supreme Court of Canada has now overturned the Promise Doctrine, thereby scaling back the potential for attacking patents by asserting lack of utility.

The Context:

For AstraZeneca, persistence in the litigation proved useful, albeit lengthy. Roughly 7 years prior to the Supreme Court’s decision, Apotex had succeeded in obtaining a Notice of Compliance (June 10, 2010), the regulatory requirement for launching a generic version on the Canadian market: (per Hughes, J., 2010 FC 714). AstraZeneca subsequently initiated proceedings for patent infringement, while Apotex responded with a counterclaim for patent impeachment based on lack of utility.

Both the trial judgment of Rennie, J (2014 FC 638) and appeal divisions of the Federal Court (Dawson, Ryer and Webb JJ.A., 2015 FCA 158) agreed with Apotex that the patent was invalid for want of utility. While the patent promised both utility as a proton pump inhibitor (PPI), and effectiveness for a wider range of persons, with less interpatient variation, the second promise, (less variation in patient response) was unfulfilled at the filing date because it was neither demonstrated nor soundly predicted. (As would be known to readers, for sound prediction to exist, there are three requirements: a factual basis for the prediction, an attributable and sound line of reasoning from which the desired result can be inferred from the factual basis, and proper disclosure. The last requirement was also overturned by the Supreme Court in this decision). The lower courts held that as one of the two promises described in the patent was not met, the patent as a whole was invalid for lack of utility.

The Final Result: Patent held to be Useful, Valid and Infringed

The key issue on appeal to the Supreme Court of Canada was whether the Promise Doctrine established the correct standard of assessing utility. As the Court explained, if correct, the Promise Doctrine could invalidate
an entire patent for lack of utility if any one of multiple uses disclosed on in the specification, i.e. both the claims and the disclosure, is neither demonstrated nor soundly predicted at the time of filing. The Supreme Court of Canada allowed the appeal, overruling the Promise Doctrine, and finding that the patent was both valid and infringed. In particular, the claimed invention was held to be useful because it was soundly predicted to be useful as a proton pump inhibitor. Although the patent may have promised more than it could provide, “promises are not the yardstick against which utility is to be measured” (para. 63).

The Supreme Court of Canada concluded that it would be unduly onerous to hold an entire patent invalid because not every promised use expressed in the patent was sufficiently or soundly predicted at the filing. The approach is “antagonistic to the bargain on which patent law is based wherein we ask inventors to give fulsome disclosure in exchange for a limited monopoly”. A patent assures exclusivity for a limited period in respect of practical solutions to practical problems, encouraging public disclosure for society’s benefit.

The decision provides guidance on drafting applications, interpreting and enforcing patents. Although the Patent Act provides that a patentee must establish that the subject matter of the patent has “utility,” utility is no longer determined by reference to the Promise Doctrine. Rather, as the Court explained, the correct approach to determining whether a patent has the requisite utility as is required under s.2 of the Act entails a two-step analysis (paras. 54-55):

1. identify the subject matter as claimed in the patent; and determine whether the subject matter is useful, that is whether it is capable of a “practical purpose” or an actual result. If so, a scintilla of utility will do (para. 55).

Although the framework leaves future lower courts to work out the nuances of the analysis, the decision answers some key questions about utility in Canadian patent law. First, where should one look to find the subject matter of an invention? To the claims. Second, how much utility is required? One single practical use suffices.

**Good Faith and the Bargain Theory**

The decision should not be interpreted as doing away with a general duty to act in good faith when drafting patent applications. Section 53 of the Patent Act requires an applicant to be honest and complete in the description of the invention. Section 73(1)(a) of the Act requires the applicant to respond in good faith to the Patent Office, failing which the patent becomes abandoned. As noted in the AstraZeneca decision, the mischief associated with overpromising could be approached under different facts in a number of ways, including declaring an overly broad claim invalid or declaring the patent void under s. 53 of the Act if the overpromising is made willfully for the purpose of misleading.

Disruptive innovations offer the promise of rendering health care solutions simpler, more convenient, and more affordable. The patent system is seen by some as a barrier to simplicity and by others as the gateway through which inventions are “coaxed” into public reach. The AstraZeneca decision is a welcome addition to precedents which simplify patent interpretation, enforcement, and as a practical matter, the responsibilities of the patent practitioner.

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Stacy Rush, Associate at rideout & maybe LLP in Toronto
Yael Bienenstock, Counsel at Torys LLP in Toronto
Teva Abandons Opposition but Application Ruled Invalid Anyway

Astellas Pharma filed Israel Patent Application No. 178249 titled “Pharmaceutical Composition for use in Solid Formulation Crystalline Solifenacin or Salt Thereof and a Process for its Preparation”. The Application was the national phase of PCT/JP/2005/005377 which was filed on 24 March 2005 and claimed priority from a couple of earlier US provisional applications.

The Application relates to a solid pharmaceutical containing Solifenacin or Solifenacin Succinate that is up to 77% amorphous as determined using NMR.

The Application was allowed, and on 27 February 2002 Teva Pharmaceuticals submitted an Opposition. On 26 June 2013, Astella requested permission to amend the specification. Teva opposed some of the amendments and in an interim ruling of 19 May 2014 Ms Jacqueline Bracha approved some of the amendments, which were then published for Opposition purposes, and since no oppositions were submitted, were then allowed. This ruling relates to the amended specification.

On 29 July 2015, instead of submitting an amended statement of case, Teva abandoned the Opposition. Nevertheless, on 27 March 2016, in a detailed ruling, Ms Bracha explained to Astella that under the Authority granted by Section 34 of the Law, she was refusing to grant the patent. The ruling was based on two publications that Teva had submitted in the Original statement of case that showed that persons of the art would expect the rate and degree of solubility to increase with increased amorphousness of a tablet. On 22 May 2016 the Applicant requested an oral hearing which was held on 4 January 2017 and this ruling follows that hearing.

Applicant’s Claims

Astellas, represented by Gilat Bareket, claimed that in a Section 34 proceeding, the burden of proof is on the Commissioner. The claim that since the Opposition was abandoned and following allowance by the Examiner, there is an assumption of validity. Therefore, the Commissioner has to overcome this rebuttable assumption.

The Applicant claims that the prior art describes a process for fabricating Solifenacin hydrochloride crystals. It did not relate to amorphous Solifenacin or to degradation of the amorphous Solifenacin or to medical formulations comprising Solifenacin Succinate.

The Applicant claims that there is a continuous decrease of the active ingredient due to degradation which they determined to be due to the amorphous Solifenacin that is produced in when preparing the tablets.

The Applicant clarified that restricting the amount of the amorphous Solifenacin to no more than 77% increases the stability and reduces degradation to rates tolerable in Japan. Furthermore, the Applicant found that when the fabrication process is wet granulation they can control the amount of amorphous material by controlling the moisture
levels. They also claim that using PEG as a binder also lowers the degradation, however the Deputy Commissioner notes that this was not claimed and is thus not part of the invention.

As stated, the invention is intended to provide a stable formulation with less than 0.4% degradation of Solifenacin Succinate in the total amount.

The discussion related to the following publications:


### The Burden of Proof

The Applicant alleges that the burden of proof resides with the Commissioner. In Y Kedmi “On Evidence”, 4th Edition 2009, it is stated that the burden of evidence depends on the substantive law:

The determination regarding which side bears the burden of proof depends on two basic principles:

- “The one seeking redress has the burden of proof” [Baba Kama 46a] and this may be plaintiff or the defendant, depending on circumstances.
- “Evidence follows the Substantive Law” – both when establishing the basis of the legal claim / defense, and when overcoming presumptions.

As a general rule, the burden of proof that a patent application is registerable is on the Applicant see 665/84 Sanofi ltd. vs Unipharm ltd. p.d. 41(4) 729 and Appeal 645-06-13 Unipharm vs. Lilly Icos, 26 January 2014.

The Opposition is considered as a completion of the Examination, and the allowability is reconsidered. It serves to protect the integrity of the register and the executive examination, see Opposition of IL 136482 Bromium Compounds Ltd vs. Albermarle Corporation USA, 7 November 2010:

*It appears that the attitude of the court has changed since then. Now the Supreme Court sees the Opposition process as a completion of the executive examination that is designed to ensure the public interest and the integrity of the register.*

The public interest that the Opposition proceedings serves is detailed in 2826/04 Commissioner of Patents vs. Recordati Ireland Ltd. p.d. 59(2) 85.
The purpose of the Section 34 proceeding is identical to that of Oppositions, i.e. to maintain the integrity of the register, see the Section 34 ruling concerning IL 156034 Serguei Borisovich Sivolovenko vs. Diamcad NV, 25 January 2015:

The Section 34 proceeding is another hurdle that the Applicant may have to negotiate before receiving a patent. During this proceeding, the Commissioner is allowed to consider all the material before him from the Opposition proceeding, and to decide whether to uphold the Examiner’s decision or to change it. The purpose is no different from that of Examination or Oppositions, and is to protect the integrity of the register and the public interest to not issue patents contrary to Section 3 of the Law. Successful negotiation of the Examination stage does not bestow a right to a patent.

The patentee’s right to a monopoly for the patented invention is in rem. Consequently he has to show that the invention fulfils all the requirements of patentability under the Law. The burden of proof only changes once a patent issues. This was clarified by Commissioner Kling in IL 142896 and IL 179379 Medice Arzneimittel GmbH & Co. KG Alkermes Pharma Ireland Ltd, 4 April 2017.

In a cancellation proceeding, the burden of proof that a patent is invalid is on the Requester for cancellation. For example, this was established in Appeal 8802/06 Unipharm ltd. vs. Smithkline Beecham PLC, 18 May 2011:

Section 37 of the Law completes this idea by establishing that Examination and granting of a patent do not guarantee it has validity. So the issuance of a patent by the Commissioner does not create a non-rebuttable assumption of validity. It merely establishes that the Commissioner considered it issuable. (appeal 47/87 Hasam Systems for Defence of Trustworthiness ltd. vs. Bahari, p.d. 45(5) 194, 201-202 (1991). However, the burden of proof that an issued patent is invalid is on the party claiming invalidity (See Appeal 665/84 Sanofi vs. Unipharm ltd. p.d. 41(4) 729, 736 (1987), Appeal 700/78 Isisco International Company for Solar Energy Systems ltd. vs. Banit, p.d. 34(1) 757, 763 (1979).

Thus, before a patent issues, the burden of proof is on the Applicant.

Validity of Patent Application

On page 2 of the Application, the Applicant notes that solifenacin was known as was its efficacy for treating diseases of the urinary tract, salts of solifenacin and the crystalline state of solifenacin hydrochloride and methods of manufacture.

Solifenacin Succinate was used in Vesicare, see accompanying flyer which was published in December 2004, before the priority date of the present application. The synthesis of Solifenacin Succinate is also described in the prior art (Appendix 3 of the Opposer’s Statement).

The Applicant claims that during development of the formulation they discovered that there is degradation where the amorphous state is present. The Applicant claims that the prior art was unaware of this phenomenon and thus did not address it.

Appendix 9 page 1137 teaches that exposure of solid pharmaceuticals to high moisture results in degradation:
“It is widely recognized in the pharmaceutical field that exposure of solid drugs (small molecules or proteins) to high relative humidity and the resulting association of water vapor with the solid generally accelerate the rate of chemical degradation.”

Further on it is mentioned that the instability typically occurs in the amorphous part of the formulation:

“...most instabilities observed for drugs occur in solution much more readily than in the solid state; when they do occur over practical time scales in the solid state, it is very likely that the reaction is taking place in the more disordered amorphous regions of the solid.Indeed, it has been shown in a number of cases that under otherwise identical conditions reactivity of a particular substance in the amorphous state is greater than that in the crystalline state.”

Appendix 11 teaches that in cases where the active ingredient is found in an amorphous form, this is likely to accelerate the degradation. However, sometimes, the amorphous form spontaneously crystallizes:

“The high internal energy and specific volume of the amorphous state relative to the crystalline state can lead to enhanced dissolution and bioavailability, but can also create the possibility that during processing or storage the amorphous state may spontaneously convert back to the crystalline state.

...In the first, a material may exist intrinsically in the main amorphous state or it may be purposefully rendered amorphous and we would like to take advantage of its unique physical chemical properties. Under these circumstances we usually want to develop strategies to prevent physical and chemical instability of the amorphous sample. In the second case, we may be dealing with a crystalline material that has been inadvertently rendered amorphous during processing. This type of amorphous character usually exists predominantly at surfaces at levels not easily detected and has the potential to produce unwanted changes in the physical and chemical properties of the system. In this situation we usually want to process the system so that the amorphous portions of the solid are converted back to the most thermodynamically stable crystalline state.”

The Application describes attempts by the applicant to prove that there is a connection between the amorphous state and the results of degradation F1 (table 2 on page 38 of the Application.

The Applicant compared the stabilities of samples 1-4 that included 63%, 73%, 715 and 7% amorphous material, with samples 1-3 that contained 92%, 90% and 92% amorphous material. However, the results of table 2 do not show a clear correlation between the amount of amorphous material and the F1 decomposition product. For example, example 1 had 63% amorphous material but only 0.31% F1, whereas example 2 had 73% amorphous material but only 0.29% F1, and in comparative sample 1 with 92% amorphous material there was 0.48% F1, and in comparative sample 3 with 92% amorphous material there was 0.4% F1.
Furthermore, as can be seen from table 2, the moisture of the granulate influences the F1 breakdown product, and can at least partially explain the difference between the results of comparison samples 1 and 3. The Applicant claims that there is some correlation between the water content of the granulate and the amount of amorphous material but it is not certain that the amorphous material content influences the amount of F1 degradation product.

Furthermore, it appears that the 0.4% limit that the Applicant set was based on the Japanese Health Ministry requirements and was not empirically determined. The Applicant admits that the Japanese acceptable limit was 0.5% and 0.4% is preferable. Table 2 shows that even where the amorphous quantity exceeded 77%, less than 0.5% of F1 was obtained.

Even if we assume that the Japanese Ministry of Health limits are desirable, the applicant has not established that there is a problem attaining these limits that the invention overcomes, due to the stability of the salt. The 77% amorphous material limit is also not empirically established. The Applicant was not able to produce Solifenacin Succinate with more than 0.5% F1 degradation product, and there is no linear connection between moisture content and amorphous material content.

Applicant does not deny that amorphous Solifenacin Succinate can spontaneously crystallize (see Appendix 2 and letter of 5 December 2012 and “Analysis of Appeal in European examination file from 17 April 2012 that the Applicant submitted in the corresponding European application. The slight differences in F1 product are even less significant due to this spontaneous crystallization.

There are a few more paragraphs regarding the various compositions and the binder (that wasn’t claimed and then, the Deputy Commissioner states that) from another angle, Appendix 9 teaches that there is a close connection between moisture and the amount of amorphous material present – page 113:

“Generally, for reactions occurring in the amorphous solid state, the rate of reactivity increases with increasing water content, and this can be attributed to the ability of the amorphous solid to absorb water vapor into its bulk structure, forming an amorphous solution. In a few cases it has been reported that a certain amount of water must be present to ensure chemical stability, e.g., lipid peroxidation rates decrease with the addition of small amounts of water; however, a destabilizing effect of absorbed water is more generally the case for the major types of drug degradations, e.g., hydrolysis, oxidation, or deamidation.”

So it seems that average persons of the art at the time in question would conclude that limiting moisture would limit the amorphous material in the formulation and this would, in turn, limit degradation. Consequently, this has no inventive step whatsoever.

CONCLUSION

The invention is wholly lacking in inventive step and so the IL 178249 Application is rejected.
COMMENTS

I am not a pharmacist, but have a fairly strong background in chemistry. It seems to me to be fairly obvious how to control the crystallization rate and extent, and how this will affect solubility. Possibly high school thermodynamics is inadequate, but a basic undergraduate course of chemical thermodynamics is more than adequate to predict this invention, so it seems to me that the Deputy Commissioner was correct to refuse the patent.

Formally, the Opposer is wrong to claim that the onus of proof is on the Commissioner. The case-law considers the Opposition proceeding as part of Examination and does not assume that the Examiner concluding that an invention is patentable establishes a presumption of validity. TEVA’s withdrawal of their Opposition may have been a commercial decision. In practice, although formally Israel requires an inventive step, an Examiner has to show anticipation or obviousness not to grant a patent. TEVA made some of the scientific literature of record, and the Deputy Commissioner was correct to relate to it.

This decision seems to be correct. However Astella, may appeal it to the courts.

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