Welcome to our IAG December 2015 Newsletter

Dear ABA-IPL Members;

Welcome to the 10th 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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UK Draft Bill published – Unjustified Threats in Intellectual Property

The main points of the draft ‘Intellectual Property (Unjustified Threats) Bill’ are:

- The Bill would effectively harmonize the threats position in relation to patents, UK and Community trade marks, and registered and unregistered designs under the UK and Community regimes. (Currently the threats regime as it applies to patents differs slightly. Under the Bill, however, the ability of holders of patents that have been declared invalid to avoid liability for threats where they had a good faith belief in the patent’s validity at the time of the threat is removed.)

- The focus of the Bill is in allowing threats to be made to primary actors (e.g. manufacturers or importers) without risk of liability for groundless threats. If you are threatening a primary actor, you will also be able to require them to cease secondary acts, such as selling (something which would take the threat outside the current exclusions).

- A threat will be actionable if it relates to proceedings for infringement caused by an act done (or threatened to be done) in the UK. This deals with the problem highlighted in the Best Buy case, but also means that non-UK rights owners and advisors will need to take extra care in relation to threats involving Community-wide rights. A threat to sue a French company in France for infringement of a Community registered design could be an actionable threat if it is based on acts done or threatened to be done in the UK.

- Certain types of communications with secondary actors (e.g. retailers) are to be allowed including, for example, to enable rights owners to discover whether a primary act of infringement has taken place and, if so, by whom.

- Happily, liability for legal advisors acting on client instructions will be abolished.

The draft Bill itself is very wordy, and as a result imports into the regime concepts such as whether information included in a “permitted communication” to a secondary actor is “necessary” for the “permitted purpose”. This may lead to litigation to clarify, as might the new jurisdictional rules. That said, the draft Bill should be welcomed at least as a more rational approach than the current regime.

For very cautious rights owners, it is worth remembering that there are still a whole host of IP rights where the threats regime does not apply at all, including copyright, plant varieties rights, geographical indications, passing off, trade secrets and database right.

The Bill is to go through the Parliamentary process “at the earliest legislative opportunity” so further amendments are still possible.

Lucy Nunn, Fieldfisher, London – lucy.nunn@fieldfisher.com
How similar are VIMEO and MEO?

*Vimeo v OHIM (Case T-96/14)*

The EU General Court has dismissed an appeal by Vimeo LLC and found that the trade mark VIMEO was confusingly similar to the earlier MEO trade mark owned by PT Comunicações, SA. PT’s trade mark was registered in the following stylization:

![meo](image)

*Similarity of the marks*

The Court made a detailed analysis of the similarity between the marks as follows:

- **Visual comparison:** while the relevant public will perceive a difference in the marks due to the stylised typeface and figurative elements of the MEO mark, and the greater number of letters and the group of letters “vi” in the VIMEO mark; they will perceive that the marks share the element “meo” and therefore perceive a certain visual similarity between them.

- **Phonetic comparison:** the marks have a certain phonetic similarity due to the fact that the letters “meo” are entirely contained within the VIMEO mark – the relevant public will pronounce VIMEO as a whole world and pronounce “meo” in the same way as in the MEO mark. The presence of the letters “vi” in VIMEO and the longer length of the word do not lead to the conclusion that there is no phonetic similarity at all between the two marks.

- **Conceptual comparison:** no conceptual comparison of the mark is possible as neither of the marks have any meaning for the relevant public. In particular, the English speaking part of the public would not give any meaning to MEO and would also not necessarily associate the term “vimeo” with the term “video”.

Vimeo also argued that the Board failed to take into account evidence showing that the marks had co-existed peacefully. This evidence included a witness statement from Vimeo’s president, extracts from the Vimeo website showing promotional events for the Vimeo platform and profiles of long-standing users of Vimeo, and copies of newspaper articles from between 2008 and 2010. The Court held that while this evidence showed prior use of the VIMEO mark, it was insufficient to demonstrate peaceful co-existence of the marks in issue, as it gave no indication as to the relevant consumer’s perception of the two signs.

Taking into account the visual and phonetic similarities of the marks, the similarities between the goods and services at issue and the ordinary distinctive character of the MEO mark, the Court concluded that the overall impression produced by the two marks could lead the public to believe that the goods and services at issue come from
economically linked undertakings. As such, Vimeo’s appeal was dismissed in its entirety and the OHIM’s decision to reject the application remains in force.

Comment
The case is an example of how technical the OHIM, and the General Court, can be when considering similarity between marks. The emphasis is often on what is common between marks rather than what distinguishes them. Here even a moderately low level of similarity gave rise to a likelihood of confusion. It is particularly notable that aspects like the length of the mark and the prefix, which many practitioners would consider to substantially reduce similarity, were not sufficient in this case. This judgment will make life even harder for those advising businesses on the launch of new brands.

For those businesses with established brands, the case also shows the high evidential threshold that must be met in order to demonstrate that the brand has been peacefully co-existing with the brands of other earlier trade mark owners.

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European Court of Justice rules on Kit Kat reference relating to shape marks and acquired distinctiveness

Following a reference from the UK High Court in Cadbury’s opposition to Nestlé’s application to register the three-dimensional shape of a Kit Kat as a UK trade mark, the CJEU issued a decision in September addressing questions relating to shape marks and acquired distinctiveness.

In relation to shape marks, the CJEU confirmed that the three grounds for refusal in Article 3(1)(e) operate independently of each other and therefore a shape mark will only be precluded from registration if one of those grounds applies to all essential features of the mark. It also held that the preclusion against registration where the shape is necessary to obtain a technical result applies only with regard to the manner in which the goods function (and not the manner in which they are manufactured).

On the issue of acquired distinctiveness, the CJEU found that mere recognition of a mark would not suffice to establish acquired distinctiveness; the mark alone must be perceived as an indicator of origin (notably, the Court did not specifically refer to ‘reliance’ which featured in the referred question).

Background

The background to this dispute, and the questions referred by the UK High Court, are discussed in a previous IP Bulletin by King and Wood Mallesons (updated following the Advocate General’s decision in June 2015).

Nestlé applied to register the following shape as a UK trade mark for various chocolate-related goods in class 30):

![Kit Kat shape](image)

The shape is essentially that of a four-fingered Kit Kat, albeit the application omits the words "Kit Kat" which are embossed on the product. Cadbury opposed the application on the grounds, broadly, that the Mark (a) was devoid of distinctive character, (b) had not acquired a distinctive character through use, (c) consisted exclusively of the shape which results from the nature of the goods themselves and (d) consisted exclusively of the shape of the goods which is necessary to obtain a technical result. In support of its claim of acquired distinctiveness, Nestlé relied upon a survey in which 90% of respondents mentioned "Kit Kat" when shown a picture of the shape mark and asked various questions.

At the UKIPO, the Hearing Officer decided (in relation to the vast majority of the goods covered by the application) that the Mark was devoid of inherent distinctive character, had not acquired a distinctive character, and that each of the essential features of the Mark consisted either of a shape resulting from the nature of the goods themselves or was necessary to obtain a technical result. On appeal to the High Court, Mr Justice Arnold opted to refer three questions to the CJEU.

CJEU Decision

Shape objections

In typical fashion, the CJEU rearranged and restated the national court’s questions. The second and third questions concerned the scope of the preclusions against shape mark registrations in Article 3(1)(e)(i)-(ii) of the Trade Marks Directive. Given that these are an absolute bar to the registrability of a shape mark, and that shape marks which fall foul of them can never acquire distinctive character for the purposes of Article 3(3), the CJEU addressed these questions first.
The CJEU first considered the second question: whether a mark consisting of three essential features, one of which relates to the nature of the goods themselves and two of which are necessary to obtain a technical result (both of which are grounds of refusal under Article 3(1)(e)), is precluded from registration. The CJEU confirmed its finding in Case C-205/13 Hauck that the three grounds for refusal in Article 3(1)(e) operate independently of each other. Therefore, whilst it is possible that the essential features of a shape mark may be covered by one or more grounds of refusal, registration may be refused only where at least one of those grounds is fully applicable to the mark at issue. This is contrary to Arnold J’s provisional view; indeed, he stated that it would be “bizarre” if a shape mark whose essential features all fall within at least one of the Article 3(1)(e) grounds of refusal could be registered, merely because none of the grounds apply to all essential features of the mark.

The CJEU then confirmed (in answer to the third question) that a shape application should be refused where the shape is necessary to obtain a technical result with regard to the manner in which the goods function. However, it should not be refused where it is necessary to obtain a technical result with regard to the manner in which the goods are manufactured. Again, this is contrary to the view expressed by Arnold J. The CJEU justified its finding by reference to the underlying objective of Article 3(1)(e)(ii) of the Directive, which it identified as preventing monopoly rights from being granted in technical solutions which consumers will seek in the goods of competitors. In particular, it observed that the method by which goods are manufactured (as distinct from the manner in which they function) is not important to consumers.

**Acquired distinctiveness**

Finally, the CJEU turned to the first question in relation to acquired distinctiveness. Arnold J had asked whether it is sufficient that a significant proportion of the relevant class of persons recognise the shape and associate it with the applicant’s goods, or - alternatively - whether consumers must rely on the shape as indicating the origin of the goods. Notably, the CJEU did not refer to “reliance” when re-stating the question, but instead referred to whether consumers perceive the goods or services designated by the shape as originating from a particular company. It concluded that mere recognition would not suffice to establish acquired distinctiveness; the trade mark applicant *must prove that the mark alone, as opposed to any other trade mark which may also be present* (i.e. in this case the KitKat word mark in particular) identifies the undertaking from which the goods originate.

**Comment**

The obvious question arising from the CJEU’s findings on acquired distinctiveness is how trade mark applicants can prove that a particular shape mark alone is perceived as an indicator of origin. This will be particularly difficult given the likelihood that shape marks are likely to be used on the market in combination with other indicators of origin such as word marks. There may be a role for survey evidence in these cases, but in any case it is clear the CJEU’s test is not straightforward and is likely to be a high hurdle for trade mark applicants.

That is not to say, however, that the CJEU’s decision is all bad news for Nestlé. In particular, it will welcome the Court’s confirmation that the grounds for precluding registration of a shape mark in Article 3(1)(e) CTMR cannot be applied cumulatively - given the findings in the national proceedings to the effect that no one of those grounds applies to all of the essential features of the Kit Kat shape mark.

The decision is therefore somewhat of a mixed bag and it is likely that both Cadbury and Nestlé could seek to claim a victory. Ultimately, however, the registrability of the Kit Kat shape as a UK trade mark will be determined when the matter goes back to the High Court for its decision.

Separately, the OHIM Board of Appeal, in its decision of 11 December 2012, upheld Nestlé’s CTM application for the same shape (albeit a different set of class 30 goods), finding that the mark had acquired distinctiveness and rejecting Cadbury’s objections on Article 3(1)(e) grounds. Cadbury’s appeal to the General Court – which was stayed pending the CJEU’s judgment in the reference from the English High Court – will now recommence.

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SMEs can access information from Ibero-American offices in one place

The platform Cibepyme is in the air (www.cibepyme.com). It aims to give support to small and medium-sized Ibero-American companies which intends to become internationalized. INPI – the agency responsible for the registration of trademarks in Brazil – offers a webpage as a result of the cooperation with the Programa Ibero-Americano de Propriedade Industrial – IBEPI (the Ibero-American Program for Intellectual Property).

In the website, the user will find all the necessary information to obtain profitable results from its innovations in the countries of the region. Cibepyme provides information, services and free assistance about IP (by a consultation form), to promote a better use of the registration systems.

Furthermore, the platform allows to share better practices, case studies where companies have committed themselves with the registration system, campaigns to raise awareness, news and actions promoted by the participating countries.

The page is produced in Spanish, and has microsites in Portugal and Brazil in Portuguese. The information in English will be available soon.

For the time being, the countries that belongs to the IBEPI are part of this initiative: Argentina, Brazil, Colombia, Costa Rica, Equador, Spain, Mexico, Paraguay, Peru, Portugal, Dominican Republic and Uruguay.

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INPI is celebrating an agreement to accelerate the process for registering Patents in US

Late this month, INPI should sign with USPTO an agreement to share information.

The aim is to accelerate the patent process for Brazilian companies that are willing to establish business in the United States. The same will happen with US companies that wants to establish business activities in Brazil.

Nowadays, the Brazilian PTO takes 10 to 14 years to approve a patent. Initially, the new project will examine 300 cases; half of them are from each country.

Tiago Rogero & Jimmy Oliveira, Geurra IP, Brazil
GoPro Faces US Cube-Shaped Design Patent Infringement Suit

The wearable-camera market has greatly expanded in the last few years. Not surprisingly, competition in this growth area has been expanding in parallel. GoPro Hero4, Garmin VIRB XE, Panasonic HX-A1, TomTom Bandit, Drift Stealth 2, Sony X1000VR, iON Air Pro 3, and Polaroid Cube (to name but a few) are all digital camera models designed to capture your every interesting moment (such as the adventures of your cat). As in the smartphone sector, great new ideas and innovative models have entered the market; but some designs look similar, or even identical, to others. And that’s where the fun begins, at least for IP lawyers…

C&A Marketing (a New Jersey Corp.) is the exclusive manufacturer, distributor, and marketer of Polaroid brand mountable action cameras. In January 2014, it launched the Polaroid Cube in cooperation with Ammunition, LLC (the studio responsible for various industrial designs such as the Beats headphones). It’s a new kind of point-of-view, mountable and wearable action camera with an iconic cubic shape. In July 2015, GoPro Inc. (a Delaware Corp.) launched the GoPro Hero4 Session, its smallest camera model yet.

C&A Marketing protected its cubic action camera design through a U.S. design patent (the “D’423 patent”). GoPro was also granted a patent at the USPTO (though not a design patent) for a “camera housing for a square-profile camera”. This latter patent was filed the day after C&A Marketing’s design patent.

On November 3, 2015, C&A Marketing filed a complaint for patent infringement and a request for injunctive relief at the U.S. District Court for the District of New Jersey, alleging that its U.S. patent D730,423 had been infringed by GoPro.

A picture is worth a thousand words: here is a side-by-side representation of the wearable cameras. On the left, the figure on the face of the D’423 patent and on the right, the GoPro Hero4 Session.

C&A Marketing alleges in its complaint that “GoPro has infringed and continues to infringe the D’423 patent by using, selling and/or offering to sell in the United States, and/or importing into the United States, the Hero4 Session discussed in this Complaint, which embodies the design covered by the D’423 design patent. GoPro’s infringing activities violate 35 U.S.C. § 271 (Infringement of patent). (…) Under 35 U.S.C. § 283, C&A Marketing is entitled to an injunction barring GoPro from further infringement of the D’423 patent".
This is the first cube-shaped product for GoPro. As shown in the picture below, the predecessors to this product (the GoPro Hero4 and the GoPro Hero 3+) share a design shape common to all GoPro’s previous cameras.

GoPro is likely to argue that the similarities between the Polaroid Cube and the GoPro Hero4 Session are limited to the basic or functional elements in the design patent; or that they relate only to the structural aspects. A defense based on lack of evidence of actual deception of consumers could also be raised (but it would be a long shot).

Although customers do believe in change and in user-friendly, easier cameras, legitimate intellectual property rights must of course be upheld. In any event, it is interesting to compare this case with the (design) patent litigation between Samsung Electronics Co., Ltd., and Apple Inc. concerning smartphones.

Following the launch of the iPhone, Samsung suddenly made a new device that was rectangular in form and had rounded corners.

Following the Polaroid Cube…

Stay tuned!

By Thomas Dubuisson (@tdubuisson), www.linkedin.com/in/thomasdubuisson/
This is the title of a new publication issued by the UK Intellectual Property Office, the contents of which are summarised below.

Orphan works are those works for which the copyright owners cannot be located. In such circumstances it is not possible to obtain permission from the owners to reproduce the works. The UK Government has introduced powers which enable the licensing of orphan works providing that a diligent search for the owner(s) has been conducted. Before a licence is granted, it is necessary to provide evidence that a ‘diligent search’ has been conducted. For films, this is particularly challenging as there are often rights in different elements of the film (e.g. screenplay, dialogue, music, set design) which belong to different right holders, or the heirs of the original right holders. This publication provides detailed guidance about such a search.

Things to consider before starting a diligent search:
- Why do you want to use the particular work? Is there an alternative available that would not require the time and expense of the search?
- Is the work actually in copyright? Check the duration and expiry dates of the various types of copyright which relate to the particular work.
- Who are the right holders? This itself requires a breakdown and identification of the rights involved.
- Where did you find the work? This may hold some clues about the possible right holders.
- Is the work already on the UK Orphan Works Register? Existing recognition of this status will save a lot of work.
- Has the work been published, broadcast or performed? If so, publishers and collecting societies may have relevant information.

Conducting a diligent search:
- A completed checklist will be required as evidence that a diligent search has been conducted. This should include a narrative of how the search was conducted and the sources consulted.
- This and other supporting evidence (e.g. correspondence) should be retained for at least eight years.
- Contact the creator first. If they are not the current owner, they will know who they transferred the rights to and any chain of ownership can be followed.
- If the creator cannot be located, then other sources should be followed up – the owners of other rights in the work may be able to help.
- As information comes to light, revisit earlier sources.

Other issues to consider:
- Failure of the creator to respond does not result in a work being orphaned.
- If the right holder is not in the UK disputed cases can only be resolved through the relevant courts or mediation, and a work will not be considered to be orphaned until this is resolved.

Making contact with possible leads and creators
- Contacting the estate of a creator – keep a record. The recipient is under no obligation to reply. If they don’t this is not an indication that the work is orphaned.
- Contacting publishers – they may have useful information if they are not the current right holders.
- Sources – the guide gives a comprehensive list of sources to be checked for the various kinds of copyright, examples of which are:
  - Orphan works registers
  - Producers Associations
• Databases of film or audio heritage and national libraries
• Standards authorities (eg International Standard Audiovisual Number) and identifiers (eg International Standard Music Work Code)
• Collecting societies
• Credits and other information appearing in the work itself
• Representative groups
• The provenance of a work (eg where it was found – it may have been donated to a library or museum and the donor may have information about the right holder)
• General internet searching
• WATCH – Writers, Artists and their Copyright Holders – a database of copyright contacts.
• Advertising for possible right holders in newspapers, radio and so on
• Copyright Hub – a creative industries led project that seeks to be a central source of information about rights ownerships.
• Online databases and catalogues
• Trace heirs to an estate through eg newspaper archives and genealogy sites
• Search for wills, many of which are now available online
• Treasury Solicitor (Bona Vacantia Division) which holds records of ownerless property as this reverts to the Crown Orphan works register
• Actors associations, trade associations, guilds and unions
• Agents and agencies
• Publishers


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Unilever brings a cancellation action based on the well known LUX registration in Iran

File Nos. 9209980226300324 9209980226300823
Judgment No. 9309970226300418 – September 14, 2015

Unilever N.V. brought a court action for cancellation of RUX registration for goods in class 03 against the Iranian Mahluran Company on the grounds of prior registration of well-known LUX (in English & Persian) registrations in Iran.

Unilever is the owner of LUX registrations from 1952 and LUX in Persian transliteration from 2004 in Iran and has widely used the trade marks in the Iranian market. The LUX soap has grown to become one of the most successful brands in the world for cleaning products, especially soaps which became well-known by the Unilever’s broad advertisement and investment activities and offered for sale in more than 100 countries of the world including Iran. The LUX trademark is of great importance to Unilever as regards to sales and income in Iran. The LUX soap is widely advertised in Iran and satellite channels which gained fame and reputation among Iranian consumers.

Mahluran Company, an Iranian company, had registered the trademark RUX (in English and Persian) for goods in class 03 from May 2003 and renewed the registration in 2013.

Unilever brought a cancellation action against RUX registration based on prior registration of LUX and fame and well-known status of the LUX trademark for goods in class 03 in Iran. Unilever has also relied upon bad faith of the Iranian company in adopting and using a confusingly similar RUX mark.

Unilever further argued that due to extensive use, advertising and investment throughout the years, the LUX mark has gained a reputation and fame which enjoys protection by article 32(h) of Patents, Industrial Designs and Trademarks Law and article 6bis of the Paris Convention.

In response to Unilever’s cancellation action, the Mahluran Company argued that:

- Rux in Persian transliteration has a prior filing date that LUX in Persian transliteration;
- Unilever has not contested the RUX registration for more than 10 years and the marks have acquired distinctiveness in the local market.
- The Lux and Rux are not confusingly similar for local consumers.

Mahluran Company also brought a counteraction against Unilever for cancellation of LUX in Persian transliteration based on its prior registration for RUX in Persian transliteration.

The Court of First Instance ruled in favour of Unilever for cancellation of RUX registration finding that the LUX trademark is well-known for goods in class 03 and has prior registration for mark in Iran.

The Court also dismissed that counteraction by Mahluran Company, holding that although the LUX in Persian succeeds the RUX in Persian registration, but the LUX trademark is a well-known mark in Iran and enjoys broad protection in law and the LUX in Persian has been extensively used by Unilever in Iran before RUX application.

Mahluran Company filed an appeal to the judgment and the Court of Appeal upheld the First Instance Court judgment without any further assertions.

By: IranTM.com – Raysan Patent & Trade Mark Agents
Federal Court issues first biologics decision under PM(NOC) regulations

Decision: Amgen Canada Inc v Apotex Inc, 2015 FC 1261

Amgen Canada Inc v Apotex Inc (2015 FC 1261) is the first decision of the Federal Court under the Patented Medicines (Notice of Compliance) Regulations relating to a subsequent entry biologic. Justice Hughes dismissed Amgen’s application for an order prohibiting the Minister of Health from issuing to Apotex a Notice of Compliance for a generic version of Amgen’s filgrastim product (NEUPOGEN®) until after expiry of Canadian Patent 1,341,537.

The only claim at issue before the Court was construed by the Court as covering a recombinant protein having an amino acid sequence beginning with Met (i.e. methionine), with the remainder of the sequence having some or all of the the sequence and some or all of the biological properties of the natural protein.

The existence and biological properties of the natural protein had been reported in a prior art publication (“Welte”), but the amino acid sequence of this protein was not reported. The Welte publication also noted the need for large-scale production of the protein because of implications in the management of clinical diseases including hematopoietic derangement or failure.

Apotex argued that the claimed invention was anticipated, since the existence of the natural protein had been disclosed in Welte. According to Apotex, Amgen could not receive a patent simply for identifying its amino acid sequence, which was “an inherent property” of the polypeptide. Apotex further argued that even though the recombinant polypeptide was different from the natural protein (since the former began with “Met”), this was merely an artifact of the way the recombinant protein was produced and did not confer novelty to the claim.

The Court rejected Apotex’s argument. Justice Hughes held that Welte did not disclose the claimed recombinant protein as the natural protein did not have “Met” at the beginning of its amino acid sequence and because the rest of the sequence was possibly, but not certainly, the same.

However, the Court did find that the claimed invention was obvious in light of Welte. While the Court acknowledged the high degree of skilled work and risk involved in developing the recombinant protein, it found that this work was not “creative work’ necessary to deserve patent protection”. In so doing, the Court contrasted the claimed invention with the work disclosed in the Welte publication, which “may well be considered an invention”.

The Court went on to consider Apotex’s allegation of inutility, which it held to be unjustified. In finding the claim in question not to include a “promise” of therapeutic utility, the Court noted that different claims can have different utilities and that the claim in question was only directed to the recombinant protein and not its uses. The Court concluded that the “promised” utility relating to the claim in issue (“to create a manufactured protein having some or all of the amino acid structure, and some or all of the biological properties of the natural protein”) had been demonstrated at the time the patent was filed.

As a final note, the Court declined to order costs against either party, as both parties had failed to make “matters clear and efficient for each other or the Court”. The Court noted in particular Apotex’s failure to drop arguments until the eve of trial.

Livia Aumand, Associate at the Ottawa office of Gowling Lafleur Henderson LLP
Federal Court of Appeal finds that PMPRB extends to Generics

Decision: Canada (Attorney General) v Sandoz Canada Inc, 2015 FCA 249

On November 6, 2015, the Federal Court of Appeal issued a rare decision relating to Canada’s pricing control regime for patented medicines administered by the Patented Medicine Prices Review Board (“PMPRB”). The Court of Appeal’s decision sheds light on the scope of the PMPRB’s jurisdiction over non-patent owners, such as generic drug companies, and addresses the constitutional validity of section 79(1) of the Patent Act.

The appeal arose from two decisions of Justice O’Reilly in the Federal Court, where the court allowed two applications for judicial review and set aside two decisions of the PMPRB.

One case concerns the generic company ratiopharm (now Teva) and its anti-asthmatic drug ratio HFA, a generic version of GlaxoSmithKline’s (“GSK’s”) Ventolin HFA®. ratiopharm sold ratio HFA pursuant to an exclusive license from GSK, which allowed ratiopharm to set the price of the drug in Canada.

The other case concerns the generic company Sandoz, a wholly-owned subsidiary of Novartis. Novartis authorized Sandoz to sell generic versions of certain Novartis drugs, although no written license agreement between Novartis and Sandoz governed these sales.

While the PMPRB addressed a variety of issues in each case, the Federal Court and Federal Court of Appeal decisions were limited to two issues: (1) whether non-patent owners, and in particular generic drug companies such as ratiopharm and Sandoz, can be “patentees” under section 79(1) of the Patent Act; and (2) whether the legislation governing the PMPRB (i.e., sections 79-103 of the Patent Act) is constitutionally valid. Notably, the decisions did not address the question of the scope of the PMPRB’s jurisdiction based on the interpretation of whether a patent “pertains to” a medicine.

“Patentee” under section 79(1) of the Patent Act can include non-patent owners

The PMPRB held that both ratiopharm and Sandoz were “patentees” and therefore fell within the jurisdiction of the PMPRB. This finding was based on the broad definition of “patentee”: “the person for the time being entitled to the benefit of the patent for that invention.”

According to the PMPRB, ratiopharm was considered a “patentee” of ratio HFA because it had the right to sell the medicine pursuant to the license agreement with GSK. Sandoz was considered a “patentee” because it had an implied license from Novartis to sell the medicines at issue.

The Federal Court found these decisions to be unreasonable and instead limited the PMPRB’s jurisdiction to patent owners. A primary focus of the Federal Court’s decision was its view that the constitutional validity of the PMPRB was rooted in Parliament’s exclusive jurisdiction over patents. Accordingly, extending the PMPRB’s jurisdiction to non-patent owners would put the constitutional validity of the PMPRB into question. Notably, the Federal Court did not expressly find that the PMPRB would be unconstitutional if its jurisdiction were extended in this manner. The constitutional validity of the PMPRB was merely put into question.
The Federal Court of Appeal disagreed with the Federal Court’s analysis. The errors included a failure to give sufficient deference to the PMPRB’s decision. While both Courts found that the standard of review in dispute was reasonableness, the Federal Court substituted its own view for that of the PMPRB.

The Federal Court of Appeal stated that a reasonableness review requires the Court to consider whether the decision under review meets the threshold of acceptability and defensibility and the lower court erred in failing to do so.

In finding that non-patent holding generics can be considered to be “patentees” for PMPRB purposes, the Federal Court of Appeal concluded that:

the extent to which a given company relies on patent protection in its overall business model as innovator companies typically do and generic companies typically do not, is irrelevant to the question whether, with respect to a particular medicine being sold, it is acting as a patentee within the meaning of subsection 79(1) of the Act.

The PMPRB is Constitutionally valid

Both ratiopharm and Sandoz argued that the PMPRB is unconstitutional at least to the extent that the PMPRB retains jurisdiction over generic pharmaceutical products. According to this argument, the current regime is one of pure price regulation, which intrudes into the Province’s constitutional jurisdiction over property and civil rights.

The PMPRB, the Federal Court, and the Federal Court of Appeal all agreed that the PMPRB was constitutionally valid at least to the extent that it has jurisdiction over patented medicines sold by patent owners.

However, the Federal Court questioned the constitutional validity of the PMPRB as it relates to non-patent owners. The Federal Court did not make any conclusions in this regard, since the Court found that the PMPRB’s jurisdiction does not extend this far.

The Federal Court of Appeal, on the other hand, took its analysis a step further and found that the PMPRB is constitutionally valid as it relates to non-patent owners. According to the Court of Appeal, there is no basis to undercut the integral connection between the PMPRB and patents when the drug company targeted holds a licence to sell a patented medicine without owning the patent. The court found that the PMPRB seeks to prevent the harm arising by reason of the existence of the patent pertaining to the medicine being sold. Therefore, nothing turns on the fact that the person exercising the selling rights does not hold the patent itself.

The disputes between the PMPRB and both ratiopharm and Sandoz, which began in 2008 and 2010, respectively, are not finished. The Federal Court of Appeal remitted the matter back to a different judge of the Federal Court to decide (1) the propriety of the $65,898,842.76 pricing adjustment directed against ratiopharm to offset excess revenues realized on the sale of ratio HFA; and (2) whether the respective patents in each case pertain to the medicines in issue. The Federal Court’s decision, and subsequent appeal decisions, on these issues may have a larger impact for the drug industry as they have the potential to rule on both the criteria for what is excessive pricing as well as the scope of the PMPRB’s jurisdiction over patented medicines under the phrase a “patent pertaining to a medicine.”

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Are Isolated Nucleic Acids Patentable in Australia?

Introduction

The High Court of Australia recently handed down the much-anticipated *D'Arcy v Myriad Genetics* case. Much of the popular press hailed Ms. D'Arcy a hero for standing up to “big pharma” and achieving a decision in which claims directed to an isolated nucleic acid were held unpatentable as lacking in proper subject matter.

This case was certainly important. But it was not as much a cause for celebration or dismay, depending on your camp, as it appeared at first blush. It re-affirmed some well-worn principles of our law relating to patentable subject matter rather than being a sweeping decision as portrayed by much of the media.

The claims in issue

It is a mistake not to understand the claims in issue. Just 3 of the 30 claims were in issue. These were independent claim 1 and dependent claims 2 and 3.

Claim 1 is short and can be recited: “An isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.”

The Statute of Monopolies

The decision concerned itself with the application of the ancient terminology, referred to in our Act, that an invention must be a “manner of manufacture” within the meaning of s6 of the Statute of Monopolies. That statute set out that all monopolies are to be void save for: “Letters Patents and Grants of Privilege for ... the sole working or making of any manner of new Manufactures within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the time of making such Letters Patents and Grants shall not use, so as also they be not contrary to the Law, nor mischievous to the State, by raising prices of Commodities at home, or hurt of Trade, or generally inconvenient ...”

Substance of the claims

The Court held that the substance of the above claim is information that is embodied in arrangements of nucleotides. The information is not “made” by human action. It is discerned. As set out in our famous NRDC case, the “manner of manufacture” requirement set out in the above statute requires that an invention be something that involves an outcome that is an “artificially created state of affairs”. In other words, it must be something brought about by human action.

The Court pointed out that claim 1 is not a claim for a monopoly over nucleic acid isolated from the cell. It could not be because the process of isolating nucleic acid from the cell for the purposes of genetic testing is a “matter of longstanding practice and diagnostic technique.” It also made the point that the fact that the isolated nucleic acid is a product which is “chemically, structurally and functionally different” from the naturally occurring DNA from which it is isolated is beside the point. The respondent had not invented and was not claiming a new method for isolating nucleic acid.

Claim 1 was considered a claim for a monopoly over the right to apply long-established methods for the isolation and amplification of specific nucleotide fragments to the isolation and amplification of a patient's naturally occurring BRCA1 gene, where and if it is found upon subsequent examination that the patient's BRCA1 gene happened to be afflicted by any of the specified mutations and polymorphisms. This is not a valid claim of a manner of manufacture.
Claims 1 to 3 were also regarded as including the products of applying any process to cells which extracts or replicates from them nucleotides which code for mutant or polymorphic BRCA1 in the sequences specified in the patent. The class of products was so large that there was a real risk that the claims would have a “chilling effect” on the use of any isolation process in relation to the BRCA1 gene. There would be an “exorbitant and unwarranted de facto monopoly on all methods of isolating nucleic acids containing the coding for the BRCA1 gene. In other words, the monopoly would be “generally inconvenient”.

A complete bar?

It is important to note that it was not disputed that a process or method of detecting the increased likelihood of certain kinds of malignancy by isolating the BRCA1 gene and examining it for the presence of any of the specified mutations and polymorphisms may be patentable subject matter as a process. But claim 1 was not a claim for any such process. It was a claim for a monopoly over isolated fragments of naturally occurring DNA.

As I mentioned above, many have taken this decision to mean that isolated nucleic acids are, in themselves, unpatentable subject matter. This is clearly not the case. Myriad’s inability to obtain a monopoly over an isolated nucleic acid was due to the fact that it had not invented such a product nor a method of isolating the nucleic acid. Simply put, the Court identified the substance of claims 1 to 3 and came to the conclusion that Myriad was attempting to obtain a monopoly over information that it had discerned. Once that was decided, it was relatively simple for the Court to come to the conclusion that claims 1 to 3 were directed to improper subject matter.

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Endnotes:
2. S18(1) Australian Patents Act 1990
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