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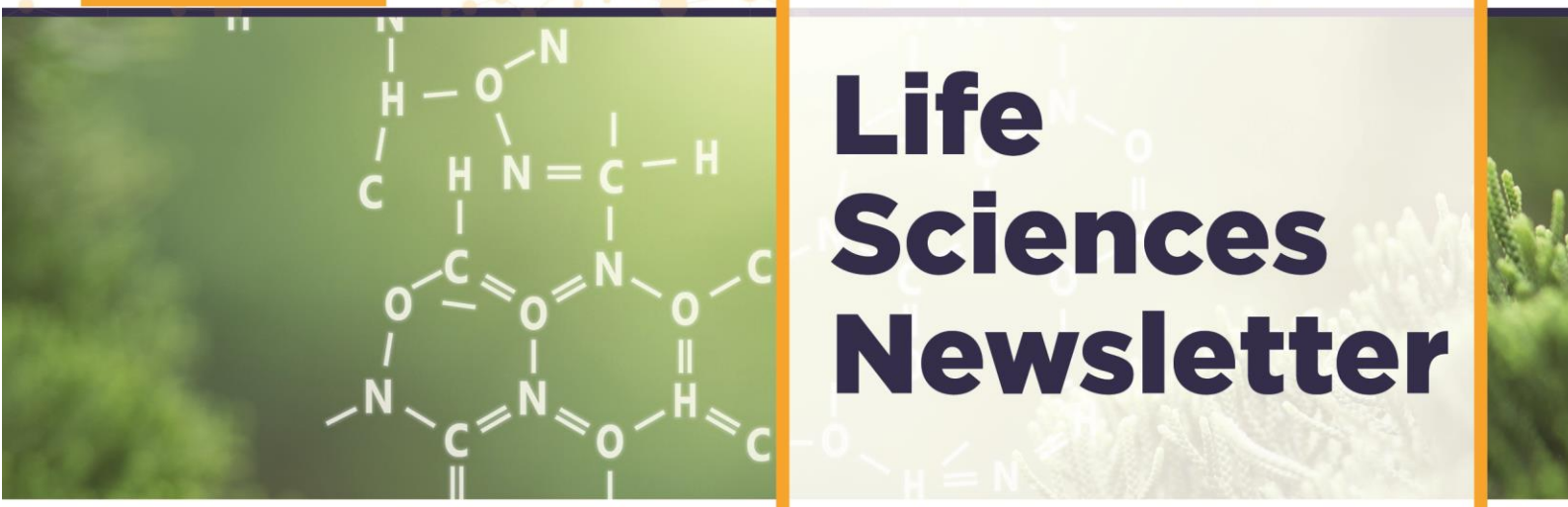
Winter 2019 Issue



Life Sciences Newsletter

In this issue:

Welcome

Welcome to the Winter Edition of the HMC Life Sciences Newsletter. Our Life Sciences team had a busy Autumn, with Marie Walsh attending the 4th China Pharma IP Summit in Shanghai, China, in October. Anna Hally attended the EPI-EPO Biotech Committee meeting in October and the CIPA Life Sciences Conference in November. Catch the team in Galway, at Medtech Rising, in December. We hope you enjoy reading our Intellectual Property matter updates.

Trends in Medical Technology Innovation and Intellectual Property

In 2018, 174,317 patent applications were filed at the European Patent Office (EPO). As illustrated in Fig. 1, medical technology is the field in which most patent applications were filed and there was an increase of 5% in filings in 2018. We note that patent application growth was also high in the life sciences of pharmaceuticals and biotechnology.

Fig. 1 Technical fields with the most patent applications filed at the EPO in 2018

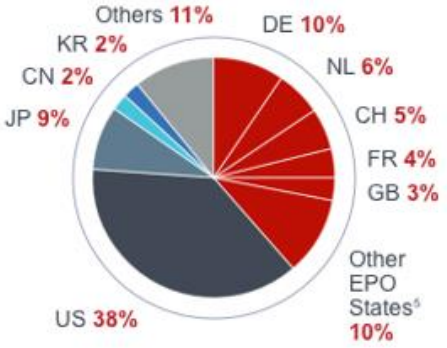


Fig. 2 Breakdown by country of origin of patent applications in MedTech in 2018

Source: EPO Annual Report https://www.epo.org/news-issues/news/2019/20190312.html

1.	JOHNSON & JOHNSON	700
2.	ROYAL PHILIPS	688
3.	MEDTRONIC	549
4.	BOSTON SCIENTIFIC	272
5.	OLYMPUS	190
6.	SANOFI	167
7.	BECTON DICKINSON	161
8.	PROCTER & GAMBLE	135
9.	FRESENIUS	130
10.	SAMSUNG	126
	Others	10 677
	Total applications in this field	13 795

Fig. 3 Top 10 applicants in the medical technology field 2018

Source: EPO Annual Report https://www.epo.org/news-issues/news/2019/20190312.html

The European Patent Office reports that eight of the EPO's top ten applicants for biotechnology patents and the top two applicants in the pharmaceutical sector came from Europe. Fig. 3 lists the top 10 applicants in the medical technology fields. It is noted that most of the patent applications in MedTech at the EPO originate in the US.

TRENDS IN THE MEDICAL TECHNOLOGY INNOVATION LANDSCAPE

There is an increasing trend across all field of technology for developments encompassing digital technology, the internet of things, and artificial intelligence. A recent report from the World Intellectual Property Organization (WIPO) identifies new fields of research and development in health as shown in Figs 4 and 5 below.

Fig. 4 New Medical Technology Trends

Source: WPIO Global Innovation Index Report 2019 https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019.pdf

Fig. 5 New Process Innovation Trends

Source: WPIO Global Innovation Index Report 2019 https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019.pdf

A further analysis of European Patent Office filing data to 2018 indicates a growing trend for convergence between traditional medical technology and digital technology including: the internet of things, digital technology and artificial intelligence.

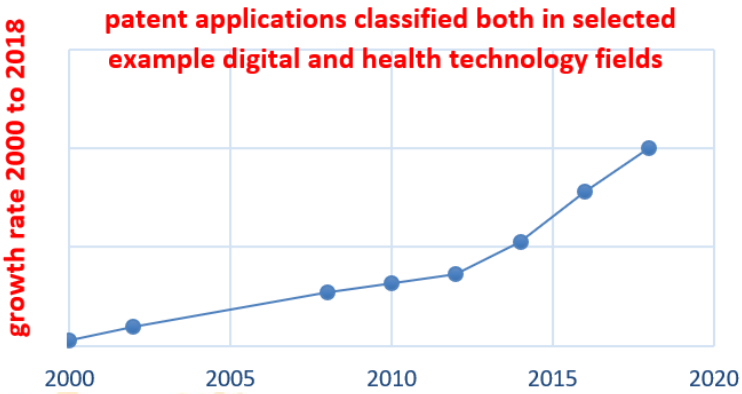


Fig. 6 Analysis of convergence across two example fields of technology

Source: EPO GPI Database

Updates to the EPO Guidelines for Examination

The European Patent Office has introduced its annual update to the Guidelines for Examination which came into force on 1 November 2019.

This year, there have been some tweaks to sections on how novelty, inventive step and clarity are assessed. The updates also add detail to discussions on formalities and procedural aspects, including helpfully giving extended examples, such as deadline calculations after resumption of proceedings.

Main changes in the Guidelines 2019 of particular relevance to Life Sciences:

Novelty of subranges

Following T261/15, the former three-step test for assessing novelty of a sub-range has dropped the last step which required assessment of whether a claimed selection is purposive. This step was considered to be more a question of inventive step than of novelty because it considers the presence of a technical effect of the claimed invention.

The now two-step test will make it easier to demonstrate novelty of claim that includes a sub-range, particularly in chemistry and pharmaceutical cases.

For details: G-VI, 8 – Selection inventions

Not enough for skilled person to "hope" to succeed

A small but significant inconsistency between the Guidelines and case law has been removed from the discussion of the EPO's problem-solution approach. The change is in the step that involves considering whether any teaching in the prior art would have led the skilled person to arrive at the claimed subject matter when trying to solve the objective technical problem.

The established case law in T2/83 sets out that it would be obvious for the skilled person to modify the closest prior art in the *"expectation of some improvement or advantage"*. However, the Guidelines previously conflated this with whether the skilled person would have modified the closest prior art in the *"hope of solving the objective technical problem"*.

"Hope" and *"expectation"* have different meanings – a *"reasonable expectation"* is based on a scientific appraisal of available facts whereas a *"hope to succeed"* is merely the expression of a wish.

By removing the phrase *"hope of solving the objective technical problem"*, the "could-would" approach has been clarified in relation to inventive step analysis.

The 2019 edition of the Case Law of the Boards of Appeal has similarly been updated to remove reference to a *"hope* to succeed".

For details: G-VII, 5.3 – Could-would approach

Obviousness in relation to biotechnology research

A new section in the Guidelines discusses what would be obvious to a skilled person in the field of biotech research, to the effect that there is no inventive step if the skilled person would have conducted research following the teaching of the prior art with *"a reasonable expectation of success"*.

The difference between a *"reasonable expectation of success"* and a *"hope to succeed"* is also clarified in the context of the research de. Specifically, if non-trivial decisions need to be made in the course of research, this goes beyond a *"reasonable expectation of success"* and may be indicative of an inventive step.

Nothing in the new section is specific to biotech research, and so it appears that this approach to inventive step analysis could be extended to other fields of research, such as pharmaceuticals.

For details: G-VII, 13 – Inventive step assessment in the field of biotechnology

Clarity of parameters in claims

The discussion in the Guidelines on assessing clarity of a product claim defined by parameters, i.e. the physical properties of the product, has been reframed. The previous version of the Guidelines firstly stated the requirement for a method for measuring the parameter values, should be recited in the claim, where needed.

Based on T849/11, the revised Guidelines discusses two additional criteria for establishing clarity of a product defined by parameters. In particular, that the claims should be clear to the skilled person without relying on the description, and that it should be ensured that *"the skilled person can easily and unambiguously verify whether they are working inside or outside the scope of the claim"*.

Further, a dedicated subsection on unusual parameters is included in the 2019 version of the Guidelines and discussed types of unusual parameters and how these can be compared to the prior art.

For details: F-IV, 4.11 - Parameters

Also of note for Life Sciences practitioners:

- Changed stance on the deletion of alternatives from more than one list – such a deletion adds matter if it results in the creation of new technical information that is not directly and unambiguously derivable from the application as filed. For details: H-V, 3.3

- Modified "essentiality test" for whether replacement or removal of a claim feature adds subject matter in contravention of Article 123(2) EPC; the test no longer requires that it be *"directly and unambiguously"* recognisable by the skilled person that no modifications are required to compensate for the replacement or removal. For details: H-V, 3.1

- Clarifications regarding file formats when filing sequence listings. For details: A-IV, 5

EPO Perspective – Priority rights in Europe – CRISPR update

As reported in our Spring 2018 Life Sciences Newsletter, the issue of priority entitlement and the problems patentees can encounter when a successive chain of title from the inventor to the applicant cannot be established now lies with the EPO Board of Appeal in the CRISPR case. This is in contrast to the corresponding US case which dealt with questions of obviousness rather than procedural issues concerning priority rights. In this case it was the failure of the Broad Institute to include a Rockefeller University inventor of a priority US patent applications in its European patent application that led to the rejection of the patent now under appeal. The Appeal hearing is scheduled for 13 January 2020, so watch this space for updates.

In the meantime, our advice remains to strongly caution applicants to err on the side of caution and ensure there is clear chain of title from each inventor to each successive applicant put in place prior to filing a PCT or European application. This is particularly important where the initial application is a US provisional application and, as in this case, there are a number of different priority applications. Problems with priority entitlement usually only come to light during post-grant proceedings, however, getting the priority claim right at the time of filing will ensure that intervening disclosures cannot be cited.

Furthermore, if getting an assignment executed before the filing of the PCT or European patent application is not possible, we would recommend ensuring the PCT or European patent application is filed in the same names as the priority application and assigned later.

European Perspective – SPC Regulation Article 3(a) – Advocate General's Opinion

Joined Cases C650/17 and C-114/18 – Supplementary Protection Certificates (EC Regulation 469/2009 – Article 3(a))

The opinion of the CJEU Advocate General, Gerard W. Hogan, was delivered on the 11th September 2019, regarding SPC Referrals C-650/17 (*Royalty Pharma*) and C-114/18 (*Sandoz v. Searle*). Both referrals concern the interpretation of Article 3(a) of the EC Regulation 469/2009. Article 3(a) of the Regulation requires the product, which is the subject of the SPC, to be "protected by the basic patent". Earlier case law has left some uncertainty around the meaning of "protected by the basic patent", specifically as to whether it requires explicit recitation in the patent claims, or if it can be interpreted as having a wider meaning. The opinion of the Advocate General, is non-binding, however the courts do consider these opinions to be strongly persuasive.

***Teva v. Gilead* C-121/17**

The CJEU of *Teva v. Gilead* (C-121/17) provided some clarification as to the interpretation of Article 3(a). In brief, Teva concerned Gilead's SPC for the anti-HIV combination therapy, Truvada. The basic patent of the SPC, EP0915894, only referred to one of the active ingredients in Truvada. A two-step test was established for determining if each of the active ingredients of a combination product covered by an SPC must be specifically mentioned in the patent upon which the SPC is based. The Teva decision provided for the establishment of the following two-step test, which was in turn established for the assessment of Article 3(a):

A product is covered by a basic patent according to Article 3(a) if, from the point of a view of a skilled person at the priority date of the patent:

(1) the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

(2) each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

However, the meaning of the term "specifically identifiable" of the second Teva question remained ambiguous.

***Royalty Pharma* C-650/17**

The *Royalty Pharma* referral originated from the German Patent Court, and relates to the SPC application for the active ingredient, sitagliptin, of the diabetes drug Januvia®, and relies on the basic patent EP1084705. Sitagliptin is a DP IV (dipeptidyl peptidase IV) inhibitor used to lower blood glucose levels in diabetics. Januvia® comprises sitagliptin, and although the basic patent claims DP IV as a functional class, sitagliptin is not individually disclosed. The SPC application for sitagliptin was refused on the grounds that sitagliptin was not protected by the basic patent within the meaning of Article 3(a) of the SPC Regulation. Three questions were therefore referred to the CJEU, by the German Federal Patent Court, seeking further clarification on the interpretation of Art. 3(a) of the SPC Regulation.

***Sandoz v. Searle* C-114/18**

The *Sandoz v. Searle* referral originated from the UK Court of Appeal, in a case relating to a revocation action brought by Sandoz and Hexal against Searle's SPC for the active ingredient darunavir and product Prezista®. Darunavir is a HIV reverse transcriptase inhibitor, covered by the claims of the basic patent, EP0810209. EP0810209 claims a generic group of compounds in the form of a Markush formula. Darunavir is encompassed in the group of compounds covered by the Markush formula, however it is not specifically disclosed in the patent. Regarding Art. 3(a) of the SPC Regulation, the UK Court of Appeal, referred the following question to the CJEU:

"Where the sole active ingredient the subject of a [SPC issued under Regulation No 469/2009] is a member of a class of compounds which fall within a Markush definition in a claim of the patent, all of which class members embody the core inventive technical advance of the patent, is it sufficient for the purposes of Article 3(a) of [Regulation No 469/2009] that the compound would, upon examination of its structure, immediately be recognised as one which falls within the class (and therefore would be protected by the patent as a matter of national patent law) or must the specific substituents necessary to form the active ingredient be amongst those which the skilled person could derive, based on their common general knowledge, from a reading of the patent claims? "

The parties of the referrals (C-650/17 and C-114/18) requested further clarification of Article 3(a), and also, if the Teva two-step test was to apply to situations other than a combination product.

Summary of the opinion of Advocate General

The Advocate General considered that Article 3(a) of the SPC Regulation does not prevent the grant of an SPC for an active ingredient which is covered by a functional definition or a Markush formula, provided that the Teva two-part test is satisfied. The Advocate General presented his view on how to apply the Teva two-part test and ultimately concluded the following:

"The two-part test must be applied form the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent;

The first part of the two-part test is not satisfied if the claims in a patent in relation to that product are not required for the solution of the technical problem disclosed by a patent;

The second part of the two-part test requires that it be established that a person skilled in the art would have been able, in the light of all the information contained in a patent, on the basis of the prior art at the filing date or priority date of the patent in question, to derive the product in question. "

As the Advocate General's opinion is not binding on the CJEU, it remains to be seen whether the CJEU will indeed follow the Advocate General's advice. It is hoped that the decision of the CJEU will help clarify how to correctly apply the *Teva* two-part test.

News in Brief – Irish Perspective

Preliminary Injunctions in Ireland – The pendulum has swung again!

After a series of decisions in recent years in the Irish Courts refusing the grant of preliminary injections (PIs) or interlocutory injunctions, the Irish Supreme Court has recently held that Merck Sharp & Dohme Corporation (MSD) should have been granted a PI against Clonmel Healthcare Ltd, a generic manufacturer, from infringing its SPC on European Patent No. 0 033 538 for a combined ezetimibe/simvastatin treatment for cholesterol, Inegy®.

This Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd Supreme Court ruling essentially overturns the High Court decision in 2018 where the PI was refused on the basis that damages were an adequate remedy in the event infringement of a valid patent was found. However, as the SPC for the product had expired before this hearing, no injunction will be granted.

This Supreme Court decision, concerning appeals on a point of law, concerned the Plaintiffs point of view that there was a divergent approach to PIs in Ireland to that of the English Courts and the Irish Court applied the standard PI test (American Cyanamid criteria) somewhat differently.

In recent years, the Irish Courts have refused PIs on the basis that damages would be an adequate remedy to the Plaintiff i.e. patent holder. However, in the case at issue, the Irish Supreme Court commented that they would have granted the PI on the basis that MSDs SPC was valid until proven otherwise.

This recent decision brings the Irish Courts in line with the English Courts, where damages as an adequate remedy is only part of the PI assessment and the remedy is quite flexible. As the SPC had expired on the case at issue, the Supreme Court noted '*it might appear to be a matter of, at best, academic interest, and then only to the specialist. However, this appeal raises important questions as to the proper approach to the application for an interlocutory injunction, which is an important remedy in many different disputes.*'

News in Brief – Irish Perspective

Nagoya protocol to the UN Convention on Biological Diversity (CBD)

Ireland is currently a signatory to the Nagoya Protocol to the UN Convention on Biological Diversity (CBD) and steps are now underway for Ireland to ratify the Nagoya Protocol.

Statutory Instrument 253/2019 has been introduced to implement the EU ABS Regulation on access and benefit sharing of genetic resources. This puts in place a legislative and policy framework that will allows Ireland to proceed towards ratification of the Nagoya Protocol.

Source:

https://www.chg.gov.ie/minister-madigan-introduces-new-legislation-to-implement-eu-abs-regulation-and-begin-process-to-ratify-the-nagoya-protocol/

Meet the HMC Team

Upcoming International Events

Galway, Ireland	Anna Hally, Catherine Hanratty, Anthony Kavanagh, Donnacha Curley and Saibh Morrissey will be attending Medtech Rising. **We would love to meet up, please let us know if you are attending!**	4-5 December 2019

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For any further specific questions, please contact any one of our European Patent and Trade Mark Attorney team at Hanna Moore + Curley. This guidance document provides general information only and does not constitute legal advice.

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