



Jumping Through Hoops

As pharmaceutical companies navigate recent changes in legislation and jurisprudence, **Johnny Chan** learns from experts about patent law loopholes – and the future of the industry.

The global pharmaceutical industry is facing numerous challenges.

The first is the claiming of DNA or peptide isolated segments. “The [*Association for Molecular Pathology v.*

the isolation of new DNA segments seems unlikely, the use of peptide sequences to initiate immune responses is gaining favour. If the isolated segments cannot be patented it may deter some from pursuing such avenues of treatment. Second,

in the field of personal medicine, diagnostic procedures for monitoring a patient’s response are very important. The [*Mayo Collaborative Services v. Prometheus Laboratories*] decision as interpreted in [*Ariosa v. Sequenom* in December 2015] has created concern amongst the innovator companies as effective protection of their inventions often requires protecting the diagnostic technique used.”

The impact of the *Myriad* and *Prometheus* decisions has been magnified by the Federal Circuit’s interpretation of the decisions. “The US Court of Appeals for the Federal Circuit (CAFC) has not looked to the public policy stated by the Supreme Court,



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- Richard Kelly, senior partner,

Oblon, McClelland, Maier & Neustadt, Alexandria, Virginia

Myriad Genetics] decision has, in the US and in the companion decision in Australia, created issues in obtaining protection for such isolated segments and enforcing the patents already obtained,” Richard Kelly, a senior partner at Oblon, McClelland, Maier & Neustadt in Alexandria, Virginia, tells *Asia IP*. “While

but has rigorously applied the decisions without considering whether this approach furthers the public policy or not. In the *Bilski* decision, the Supreme Court expressed the view that patents are important to the personal medicine field in striking the CAFC’s holding that to be patent eligible an invention must meet

the machine or transformation test. The *Ambry* and *Sequenom* decisions clearly do not further the public policy as expressed by the Supreme Court. The impact extends beyond the US because of the size and importance of the US pharmaceutical market,” Kelly says. “We have had foreign clients express misgivings about proceeding with certain research because of fear that their efforts will not be protected in the US market.”

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- Chris Hemingway, director,
Marks & Clerk, Kuala Lumpur

The solution to these first two issues lies either with the Federal Circuit recognizing that its reasoning in the *Ambry* and *Sequenom* decisions is incorrect or in a further Supreme Court review where the issue is more clearly framed than either in *Prometheus* or *Myriad*, adds Kelly.

The third challenge is the *inter partes* review (IPR) procedure in the US. “The procedure has proven to be very effective in cancelling some or all of a patent’s claims in pharmaceutical cases,” Kelly says. “The procedure places much more emphasis on correct claiming than do district court actions, whereas in the district court, the claim construction process can interpret the claims to preserve validity.”

In contrast, Kelly says that in the IPR procedure, the USPTO used the broadest reasonable interpretation (BRI), which usually means taking the claims as they are rather than what they were intended to encompass as shown by how one of ordinary skill in the art would understand them in view of the specification, prosecution history, and knowledge of those skilled in the art. The BRI standard makes it much easier to invalidate patent claims than does the claim construction approach used in court.

“The success rate of generic companies in challenging pharmaceutical patents has become of significant concern,” he says. “This issue is now pending before the Supreme Court. The pharmaceutical industry is also seeking to the law amendment to exclude pharmaceutical patents from the IPR procedure.”

A fourth issue is the challenge of biosimilars. “The Food and Drug Administration (FDA) naming convention for biosimilars will make it more difficult for biosimilars to penetrate the market,”

Kelly says. “Since the names must be different, they cannot use the generic name, [so] it will require companies to conduct an educational campaign for each biosimilar launched. Currently, no resolution is in sight.”

A fifth issue is the FDA’s decision to unilaterally allow the filing of biosimilar applications for biologics approved under the old Public Health Act, 42 U.S.C. § 262, which did not provide for any use of the company’s data in approving a third-party application for the same or similar drug.

“The tradeoff companies made for no use of their data was that under the old law there was no marketing exclusivity provided. In many cases, the company could have filed under the Food, Drug and Cosmetic Act (FD&C Act) Section 505 and received marketing exclusivity. In that case, an Abbreviated New Drug Application (ANDA) filer could rely on the innovator’s safety and efficacy data. In the case of biologics filed under this provision, the ANDA filer must show that its product was the same as the innovator’s; that is, it was interchangeable. This is a very high hurdle to clear as shown by the years-long efforts of Sandoz and Momenta

to develop a generic Lovenox,” an anticoagulant which helps prevent the formation of blood clots, Kelly says. “The problem is created by the failure of the statute to provide for any transition period for previously approved biologics.”

The Hatch-Waxman Act, in contrast, provided a transition for drugs approved under the previous law which avoided the controversy. Abbott (which is now AbbVie) raised this issue in a citizen’s petition which the FDA has not decided in the two years

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it has been pending. Abbott’s petition asserted that the FDA’s use of its data to review a biosimilar application is a taking by the government of a valuable trade secret for which it must be compensated under the Constitution. Currently, it is not clear that this issue will be pursued by the biologics license application (BLA) holders.

A sixth issue facing the pharma industry relates to supplementary protection certificates (SPC) in Europe. Currently, these certificates are issued on a country-by-country basis even when there is centralized marketing authorization. “In view of the unitary patent in Europe, the European Commission is considering the feasibility of a unitary SPC,” Kelly says. “Also with respect to SPCs, there is still confusion in the EU concerning the applicability of SPC’s for combination products where one of the drugs can receive an SPC, but the other cannot because of previous marketing. An SPC is available for the combination if the patent claims adequately specify the combination. An open question is whether or not more than one SPC is available per patent as opposed to per drug. This is important where a patent claims two compounds each of which separately receives marketing approval. The advocate general is suggesting one SPC per patent. In the US only one patent term extension is possible per patent by statute.”

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Unfortunately, the expression ‘occurring in nature’ is currently interpreted in the broadest possible manner in India.

- Ashwin Julka, managing partner,
Remfry & Sagar, Gurugon

Moreover, controversy surrounds the Trans-Pacific Pact since it only provides for five years of marketing exclusivity for biologic products, which is considered by many in the pharmaceutical industry to be too short to recover development costs, Kelly says. “As a result, the US pharmaceutical industry is not actively supporting ratification of the TPP. The only resolution is on a country-by-country approach, as the TPP allows for longer exclusivity periods for biologics but does not mandate them.”

Rahul Chaudhry, managing partner at Lall Lahiri & Salhotra in Gurugon, says that there is disparity in the patent laws in various jurisdictions in respect of claiming the “new form of known substance,” in respect of the validity of “second medical use,” in respect of the validity of “method of treatment,” etc.

“[Even when they are all part of the World Trade Organization,] there is a lot of disparity between the domestic and foreign IP laws of various countries. For instance, a second medical use patent may be validly obtained in Europe for any second or further therapeutic use of a known drug, whereas such a patent cannot be obtained in the US and India,” Chaudhry says. “Instead a ‘method of treatment’ patent may be obtained in the US. Further, unlike the US, ‘methods of treatment’ are statutorily prohibited by Section 3(i) of the Indian Patent Act, 1970, [so] the claims relating to ‘second-medical use’ in a European patent need to be changed in the US and India.”

For example, Chaudhry says that the use claim in a European patent reading ‘use of compound x for treatment of disease y’ will change in the US to ‘a method of treating a patient suffering

from disease y comprising administering an effective amount of compound x to the patient,’ while in India, a mere discovery of a new form, or new use or new property of a known substance, is not patentable, and the discovery of the new form of the known substance will be patentable only if it results in the enhancement of known efficacy of that substance. Therefore, the claims pertaining to compound x may not be allowed at all under Section 3(d) of the Patents Act in India.

Further, if the US patent application has only one independent claim, for example, ‘a method of treating a patient suffering from disease y comprising administering an effective amount of compound x to the patient,’ and has no independent claim for compound x *per se*, then it becomes difficult to amend the ‘method of treatment’ claim into a product claim in India, Chaudhry says. “Section 59 of the Patent Act prohibits such an amendment. Therefore, there should be at least one claim suiting the patent laws of domestic jurisdiction where the patent application is to be

filed. This makes it easy for the domestic jurisdiction to prosecute such claims, otherwise the patent application is liable to rejection. Therefore, there is a need for adoption of harmonized laws in respect of the second medical use claims.”

Further, there are issues pertaining to the flexibility in respect of compulsory licensing in various jurisdictions.

“Granting of compulsory licenses has been contentious for some time,” he says. “Therefore, there is a critical need to curtail healthcare costs and increase drug accessibility to the consumers. India has a strong generic pharmaceutical industry and, as a major exporter of pharmaceutical drugs to other developing countries, there is a need to make compulsory licensing an important

legal weapon so as to clearly address health problems. IP rights in various jurisdictions should aim to prevent evergreening and to protect the genuine innovators by giving them their due benefit.”

Grey Areas

Besides these challenges, there are gray areas in the existing laws across jurisdictions which could further hamper pharmaceutical development.

Malaysian patent law is largely based on the laws of the United Kingdom. In the UK, it is not uncommon for patents to be amended during litigation to avoid being invalidated, says Chris Hemingway, a director at Marks & Clerk in Kuala Lumpur. For example, Hemingway says, an independent claim may be narrowed to include the features of a dependent claim in light of a newly-discovered piece of prior art. “However, in Malaysia, the Federal Court held that due to the nature of the local legislation, when an independent claim is held to be invalid, the dependent claims will also fall, as they can only survive if the patent is redrafted to incorporate the features that they are dependent upon. Critically, this redrafting was considered to be an amendment. But unlike the UK, there is no provision in the law to allow for the amendment of the patent during litigation (Section 75 of the UK Patents Act) or to enforce a partially valid patent (Section 63 of the UK Patents Act).”

It will be appreciated that this decision may severely impact litigation by patent owners as it appears that they can no longer rely on fall-back positions in the dependent claims if the

independent claim is held to be invalid, adds Hemingway.

In India, grey areas include the applicability of the Section 3(d) of the Patent Act and various procedural grounds that make litigation difficult. "Section 3(d) recites that a mere discovery of a new form, or new use or new property, of a known substance is not patentable, and the discovery of the new form of the known substance will be patentable only if it results in the 'enhancement of the known efficacy' of that substance. However, Indian patent law needs to give better clarity and define 'enhanced efficacy' of a new form of a known substance," Chaudhry says. "In *Novartis v. Union of India & Others*, the Supreme Court of India clarified that efficacy as contemplated under Section 3(d) is therapeutic efficacy. However, the interpretation of the term 'enhanced therapeutic efficacy' remains a grey area. It is recommended to provide at least the 'in-vitro' data at the time of the filing of the complete specification, based on which external data can be provided at the time of prosecution for further corroboration."

Further, a granted patent or application can be revoked or opposed in India on procedural grounds no matter how strong

their published data is used by the biosimilar companies to seek drug approvals."

What Is Patentable?

Many have pointed to the ever-increasing complexity of patents in the life sciences field, with questions also being raised as to what constitute patentable subject matter, particularly in the biotechnology sector.

Patenting biotech inventions in India is more challenging than inventions in other fields, Julka says. "First, the inherent nature of such inventions pushes them towards the subject matter exclusions set out under the Patents Act. Second, the requirement mandating disclosure of source and geographical origin of biological materials casts an undue burden on the applicant and third, the requirement of seeking prior approval from the National Biodiversity Authority (NBA) makes for an extra, and onerous, hurdle."

Under Section 3(c) of the Patents Act "discovery of any living thing or non-living substances occurring in nature" is

barred from patentability. "A question thus arises on the quantum of human intervention/modification – genetic and/or morphological – required to differentiate a living thing from one that already exists in nature. Unfortunately, the expression 'occurring in nature' is currently interpreted in the broadest possible manner in India and the general view of the patent office is that mere isolation of a living thing or a part thereof from its natural environment – without modification that improves properties or increases efficacy does not render it patentable under Section 3(c). However, scientifically it may be argued that the moment a biological material or a part thereof is 'isolated' in the desired form from its natural environment, such

material no longer remains a living thing 'occurring in nature' and therefore does not attract the exclusion of Section 3(c)."

Additionally, Julka says, quite often the material obtained by the process of isolation is in a raw state and needs to be processed further to render it industrially applicable. Thus, the isolated material should not necessarily be excluded as a 'merely discovered living thing,' Julka says. "But as matters stand, to secure a claim directed at biological materials (in general and for antibodies), it is necessary in India that such material is a modified entity (i.e. a genetically engineered entity) rather than one merely isolated and purified. Since the Guidelines for Examination of Biotechnology Applications for Patents issued by the patent office in March 2013 are silent on the above, we look forward to valuable direction resulting from judicial scrutiny of the issue."

Another provision affecting biological processes is the exclusion under Section 3(j). Statutorily, plants and animals in whole or in part (including seeds), as well as transgenic plants and animals, are not patentable under Section 3(j). Also proscribed are "essentially biological processes" for the production or propagation of plants and animals. The inherent ambiguity surrounding what qualifies as an "essentially biological process" is reduced somewhat by the Guidelines that offer illustrative examples; however, they fail to address if, and how, human intervention can alter the character of such process. Judicial intervention has helped,



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Finnegan, Henderson, Farabow, Garrett & Dunner, Washington

the patent is. These grounds are the non-compliance of section 8(1) and 8(2) of the Patent Act, says Chaudhry.

Another grey area is the delay in the grant of applications and the lack of transparency of such delay. "On an average it takes around four to five years for a patent application to be granted," Chaudhry says. "Further, unlike the US and Europe, we have no provision to extend the validity of the patent in case of delays."

Until recently, the rationale that a basic compound patent would subsume within its scope future salt/polymorphic forms so as to bring such salts, etc, within its reach for infringement purposes (even though such salts, polymorphs may be claimed in separate and subsequent applications) was also a grey area. "In late 2015, [through] *Merck v. Glenmark* (the Sitagliptin case) and *Roche v. Cipla* (the Tarceva case), the Delhi High Court affirmatively expounded on the above," says Ashwin Julka, managing partner at Remfry & Sagar in Guragaon. "However, with the Supreme Court recently admitting the appeal on the Sitagliptin case, the greyiness of this issue will remain until the matter reaches finality."

Another issue which is turning global attention is whether, despite discretion vesting with the drugs authorities to abbreviate or omit clinical trials, that discretion can either be of advantage to the biosimilar version of an innovator's reference drug or not, says Bikita Sharma, a partner at Singh & Singh Lall & Sethi in New Delhi. "In India, data exclusivity is not recognized statutorily. Therefore, this issue becomes significant to the innovators as



Julka says. “In *Monsanto Technology v. Controller General of Patents*, the IP Appellate Board (IPAB), while upholding the decision of the Controller against grant of patent to Monsanto, overruled the patent office’s finding that Monsanto’s claimed process was an ‘essentially biological process’ and held that an act of human intervention on a plant cell and production of some changes (technical) in that plant cell was considered enough to render Monsanto’s process claims patentable. The significance of this aspect of the decision becomes more apparent when contrasted with the well-known ‘broccoli and tomato cases,’ wherein the European Patent Office’s board of appeal held that a process for production of plants comprising the steps of crossing and selection is excluded from patentability even if it contains an additional step of a technical nature.”

In the US, the case law interpreting 35 U.S.C. § 101 has expanded, but the scope of patentable subject matter has narrowed. Beginning with *Mayo Collaborative Services v. Prometheus Laboratories*, the Supreme Court started scrutinizing biotech related patents under Section 101. As a result, subject matter long thought patentable by pharmaceutical and biotech companies, as well as the USPTO, is no longer being afforded patent protection. This result, as the Federal Circuit noted, may discourage further development in certain therapeutic areas, says Emily R. Gabranski, an associate at Finnegan, Henderson, Farabow, Garrett & Dunner in Washington.

Historically, patentability under Section 101 was assessed permissively and was rarely scrutinized by courts. This is consistent with the language of Section 101, which broadly sets forth what should be considered patentable subject matter as opposed to listing certain categories of inventions as patentable or not: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title,” says Sanya Sukduang, a partner at Finnegan, Henderson, Farabow, Garrett & Dunner in Washington. “Indeed, when analyzing Section 101, earlier Supreme Court cases acknowledged that Congress ‘plainly contemplated that the patent laws would be given wide scope,’ and thus presumed that ‘anything under the sun that is made by man’ should qualify as patentable subject matter under Section 101. The only exclusions to this broad principle are patents directed to laws of nature, natural phenomena, and abstract ideas.”

However, beginning with *Bilski v. Kappos*, the scope of patentable subject matter under Section 101 returned to the spotlight in the context of business method patents. “Although recognizing that Section 101 is a threshold test and that inventions must still meet the statutory requirements of Sections 112, 102, and 103, the court’s *Bilski* opinion opened the door for potential infringers to argue that patents, beyond those directed to business method and computer related inventions, were directed to unpatentable subject matter,” Grabanski says. “This led to the Supreme Court revisiting the scope of patentable subject matter, this time in the biotechnology area, in *Mayo*. The court concluded there that the patented method – determining the amount of thiopurine to administer to a patient based upon levels of a metabolite in the patient’s bloodstream – was directed to a natural phenomenon and therefore unpatentable under Section 101. In doing so, the court set forth a two-part test for determining patent eligibility: First, courts must determine whether the claims at issue are directed to a natural law, natural phenomenon, or abstract idea. If the first part of the test is satisfied, courts then consider what additional elements are in the claims and

whether they transform the claim into patent-eligible subject matter. Subsequently, in *Ass’n for Molecular Pathology v. Myriad Genetics*, the Court further expanded Section 101’s reach, holding that isolated DNA sequences were products of nature and not patent eligible.”

The expansiveness of the Supreme Court’s decisions in *Mayo* and *Myriad* came to a head in *Ariosa Diagnostics v. Sequenom*. “In *Sequenom*, the Federal Circuit found unpatentable, under Section 101, Sequenom’s patent to an undisputedly ‘groundbreaking’ non-invasive prenatal diagnostic testing method. Concurring in *Sequenom*, Judge Linn noted that he joined the majority ‘because I am bound by the sweeping language of the test set out in *Mayo*,” Sukduang says. “Judge Linn further stated that the majority’s decision ‘represents that consequence – perhaps unintended – of that broad language in excluding meritorious invention from the patent protection it deserves and should have been entitled to retain.’ Indeed, according to Judge Linn, ‘[b]ut for the sweeping language in the Supreme Court’s *Mayo* opinion, I see no reason, in policy or statute, why this groundbreaking invention should be deemed patent ineligible.’”

The Federal Circuit’s decision to deny Sequenom’s request for rehearing en banc included a concurring opinion from Judges Lourie, Moore, and another by Judge Dyk, both indicating that the Federal Circuit was ‘bound’ by the decision in *Mayo*. “Judge Lourie, echoing Judge Linn’s prior concurrence, stated that ‘it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts.’ Judge Lourie further noted that amici have argued that ‘the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern,’” Sukduang says.

As outlined in *Mayo*, *Myriad*, and *Sequenom*, inventions related to new diagnostic methods face the greatest threat under the Supreme Court’s Section 101 jurisprudence. “This has come at a particularly inopportune time, as the biotech industry and the FDA are placing more emphasis on ‘personalized’ medicines, which rely on the identification and use of biomarkers and diagnostic testing,” Gabranski says. “Additionally, in recent patent litigations between brand name and generic drug manufacturers, accused infringers have made unique contentions under Section 101, including arguing that claims directed to methods of treating a disease by administering a pharmaceutical composition are unpatentable because the manner in which a drug works within the human body is a natural phenomenon. These arguments, however, have yet to prevail.”

The USPTO has also been grappling with the Supreme Court’s interpretation of patentable subject matter. In 2014, the USPTO published Guidance on Subject Matter Eligibility, which included two new analysis procedures for patent applications: “full eligibility analysis” and “streamlined analysis” based on the Supreme Court’s recent decisions, Sukduang says. “After feedback from patent practitioners and applicants, particularly commenting on the very broad reading the USPTO applied to Supreme Court precedent, the USPTO published revised guidance in July 2015, adding new eligibility examples intended to assist the USPTO examiners and patent applicants in applying Supreme Court case law in the examination process. Notwithstanding this revised guidance, claim rejections under Section 101 have been on the rise. Success in obtaining allowance over these rejections can be achieved by conducting early interviews with the USPTO examiners, wading through boilerplate rejection language to get

at the heart of the examiner's concerns, and narrowing claims to specific genetic sequences, diseases, and compounds so as not to 'preempt' future innovation in a particular area."

The Supreme Court Justices will have an opportunity to further delineate the bounds of patentable subject matter for biotech inventions if it decides to grant certiorari and hear the *Sequenom* case, Gabranski says. "However, unless the Supreme Court modifies its interpretation of Section 101, or Congress acts to update the patent laws to further address patentable subject matter in view of new pharmaceutical and biotech innovations, patent applicants and patentees can anticipate the USPTO and accused infringers lodging additional challenges under Section 101."

Outlook

For India, more pharmaceutical infringement suits will likely be filed as corporations and generic companies try to use the current flexibilities in India's patent laws to mark their boundaries, Julka says. "Continuing to be a low-damages jurisdiction and with long wait times on obtaining a final decree, the trend of the patentee going all out for an injunction – both interim and permanent – as an effective tool for patent enforcement is expected to continue."

The role of expert evidence in deciding pharmaceutical disputes has been emphasized by the courts in recent judgments, Julka says. "So, one can expect a greater degree of caution and care from litigants while choosing expert witnesses and adducing evidence in future cases."

Also, with the recent establishment of commercial courts to

adjudicate all cases valued over Rs10 million (US\$149,000), and with the mention of IP-specific benches in the Draft National IP Policy, India is geared to allocate specialized judicial resources to patent litigations, thereby, hopefully, resulting in better and faster decisions, says Julka.

Challenge also lies in the area of claim construction. "Claim construction is a grey area as neither the patentee nor the accused infringer knows what process to follow to get the claims construed for trial. The seemingly fluid approach directed more to a layman is currently followed which does not necessarily result in proper claim interpretation," Julka says. "Thus, the opportunity lies in establishing trial procedures relating to claim construction (distinct from and prior to the trial on the merits) which will assist the court in deciding the scope of protection that can be awarded to a patentee."

Further, we may not have seen the last of the compulsory license battles yet. "The Sorafenib compulsory licensing case between Bayer and Natco impacted the Indian patent scene in a huge way with the Supreme Court refusing to interfere with the grant of the licence to Natco by the patent office in 2012," Julka says. "However, the trend, if it can be so termed, is that the patent office is becoming more circumspect in granting compulsory licenses. As evidenced in the post-Natco cases, subsequent compulsory license applications by BDR Pharma (2013) for Bristol Myers Squibb's anticancer drug Dasatinib, and by Lee Pharma (2015) for AstraZeneca's diabetes drug Saxagliptin, were refused at the threshold, without entering courts." **AIP**



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