

ROUNDTABLE

Patent disputes

REPRINTED FROM
OCTOBER 2017 ISSUE

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THE PANELLISTS



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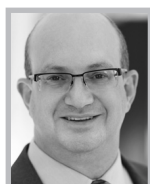
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Anthony M. Insogna is the chair of Jones Day's global IP practice. He has over 25 years of experience enforcing and defending pharmaceutical and biotechnology patents around the globe for some of the world's most successful products. Since 2012, he has navigated Idenix Pharmaceuticals LLC (a subsidiary of Merck & Co.) in global battles culminating in the 2016 record-breaking \$2.54bn patent infringement US jury verdict against Gilead Sciences Inc.



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FW: In your opinion, what have been the key trends and developments shaping patent disputes over the past 12 months or so?

Broyles: The key trend that continues in US litigation is petitions for inter partes review (IPR). IPRs have now become an established litigation defence strategy. This means that the average times to trial in patent litigation have steadily increased because IPRs are now an additional phase of patent litigation. Once an IPR is instituted, district courts typically stay the litigation. A case can be on hold for a few years while the IPR and any resulting appeals are resolved. Final decisions from IPRs are often appealed, even in those cases with a low likelihood of being reversed. Another trend, also related to IPRs, is the tendency for defendants to file more than one petition for IPR against a single patent.

Collier: The first trend actually began last year, with the Supreme Court's decision in *Halo Electronics Inc. v. Pulse Electronics Inc.* In *Halo*, the Court relaxed the standard for obtaining enhanced damages for wilful infringement, overturning the Federal Circuit's rigid Seagate two-part test that had required a finding of "objective recklessness" even where there was clear subjective intent. This subjective analysis presents uncertainty among accused infringers about the best strategy for rebutting an assertion of wilful infringement. For example, this ruling has renewed interest for accused infringers to seek a formal opinion of counsel to rebut a wilful infringement allegation. The second development, the Supreme Court's decision in *TC Heartland v. Kraft Food Group Brands*, represents a return toward the trend of rulings that give the perception of making it more challenging for patentees to assert their rights.

Reisman: The landscape of patent litigation in the US shifted dramatically with the Supreme Court's decision in *TC Heartland v. Kraft Foods Group*. This decision likely will continue to influence patent litigation for decades to come. In *TC Heartland*, the Supreme Court limited

the previously expansive venue provision that governs where a patent infringement lawsuit can be filed. Now, a domestic corporation accused of infringement may only be sued in its state of incorporation or in a state where it has committed acts of infringement and has a regular and established place of business, instead of being subject to suit, as per the previous view of the law, wherever the corporation would be subject to personal jurisdiction.

Nemec: In the US market, the single largest development in the past 12 months has been a change in the law governing where patent infringement suits may be filed. Whereas the longstanding rule gave patent plaintiffs virtually free reign to select a venue for their infringement suits, the Supreme Court decision in *TC Heartland* has now restricted venue choice to those districts where the defendant is incorporated or maintains a regular place of business. The flexibility plaintiffs enjoyed under the old rule gave rise to patent litigation hotbeds, such as the Eastern District of Texas, which plaintiffs chose because of the perception that the judges and juries in those districts favoured plaintiffs and tended to award significant damages.

Knowles: In the US, there are several key trends. One is the continued increase in the use of third-party patent challenges at the US Patent Office, where issued patents are litigated at the Patent Trial and Appeal Board (PTAB) instead of court, using a lower standard of review and resulting in a significant percentage of patent cancellations. This is good for potential infringers as it increases the possibility of freedom to operate, but bad for companies which have significantly invested in certain kinds of innovation, such as electrical, computer, mechanical and business methods. A second trend is the continued activism by the US Supreme Court in patent cases, which in the 2016 to 2017 term issued five decisions, at least partially overturned the US Court of Appeals for the Federal Circuit in all of them, and has already granted certiorari to hear two more patent cases next term.

Insogna: One key trend is the significant impact the America Invents Act (AIA) has had on patent disputes. Although the number of district court filings has declined, we are on track for a record number of IPR filings in 2017. Another trend is lower damages awards. 2016 saw the largest patent infringement verdict in US history in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, in which Idenix was awarded \$2.5bn by a jury for infringement of a patent relating to a hepatitis C drug. Yet, the overall trend is lower damages awards in most industries, as well as downward modifications of damages awards on appeal.

Cross: In the EU, preparation for the Unitary Patent (UP) has been the key development, with both EU and US-based firms developing their litigation teams in the expectation that the Unified Patent Court (UPC) will become a major forum for international patent litigation. For US firms, this may have been driven by a perceived weakening of the US patent system by the IPR procedure and patentability exclusions following the *Alice* and *Mayo* decisions. Currently, progress is on hold, pending a legal challenge to Germany's ratification of the UPC Agreement, and doubts have been raised about the effect of Brexit on the UPC, but there is political momentum for the UPC both in the EU and the UK, so we will likely see the Unitary Patent come into effect some time in 2018.

Donoghue: The Supreme Court has created the biggest patent trends over the last year. Without going into the specifics of the decisions, the Supreme Court seems to be rejecting the notion that the Federal Circuit may treat patent law as different than other tort law and requiring broad, factor based tests that give district court judges considerable discretion to come to just outcomes, over the Federal Circuit's preferred bright line rules. Another way to categorise the Supreme Court's shift is away from decisions that provide business certainty but sometimes unjust outcomes, to broad standards that delay certainty in exchange for improving justice.

FW: To what extent have you observed an increase in the number of patent disputes in today's business world? What are the most common causes of conflict?

Collier: The effect of *TC Heartland* will be interesting to observe in this respect. One would expect to see a decrease in suits filed, as patent owners may re-evaluate their likelihood of success, and thus, the logic of whether to file, where their options for filing a suit, especially in jurisdictions that are perceived as being more patentee friendly, are more limited. It is too early to tell whether this prediction will be borne out, but logic indicates that it is a fair bet.

Reisman: The past year has seen a slight decrease in overall district court-based patent litigation filings in the US, but patent disputes continue apace, as IPR challenges and other forms of patent dispute resolution have displaced district court litigation in some instances. Patentees may be less aggressive in asserting patents, perhaps concerned by the possibility of IPR or covered business method (CBM) review before the PTAB. Courts and the PTAB have shown a willingness to aggressively apply the Supreme Court's *Alice* and *Myriad* two-step test for patentable subject matter under section 101, and often rule that the contested patent is invalid. In the pharmaceutical sector, patent disputes continue apace, as there continues to be a market-driven need to slow generic competition.

Nemec: The data shows a decline in the number of patent cases this year as compared to last, though patent suits remain prolific. I believe the decline is particularly attributable to IPR, CBM and post-grant review (PGR) procedures now available to quickly and efficiently challenge patent validity before the Patent Office. Together with recent cases limiting the scope of patentable subject matter, this has put a chilling effect on many non-practicing entities, which often assert 'business method' and software patents that have become particularly susceptible to validity challenges.

Knowles: One example is the US Biologics Price Competition and Innovation Act (BPCIA), which creates an expedited market pathway for a biologic that is 'biosimilar' to or 'interchangeable' with a Food and Drug Administration (FDA) licensed innovator product. The first product, Zarxio by Sandoz, was approved in 2015. BPCI includes complex regulations that govern when the follow-on company can rely on innovator data for approval, and when the innovator can sue. The interpretation of the regulations will be heavily litigated over the next few years by drug companies. The litigation over biologics has big stakes. According to a report by Grand View Research, Inc., the US biologics market is anticipated to reach \$400bn by 2025.

Insogna: Pharmaceutical patent cases filed under the Hatch-Waxman Act have been on the rise over the past few years, though that number was down slightly in 2016. In a related arena, there has been an increase in pharmaceutical patent cases involving biologics. There have only been a handful of cases filed thus far under the BCPIA, but many more are expected in the coming years. Competition, whether in pharma, high tech or consumer products, tends to create conflict, and patent cases are one of the ways companies may try to address their competition.

Cross: We are seeing an increase in activity by patent licensing companies in Europe, particularly around standards-essential patents, and in technical areas other than mobile cellular. This often gives rise to disputes about the value of the licence and the validity of the patents, and can lead to litigation if the licensor's bluff is called. For example, in the *Rovi v. Virgin Media* cases in the UK, all 11 litigated patents were found to be invalid.

Donoghue: The number of filed patent litigations is down. And since the Supreme Court took the *Oil States* case, the number of Patent Office post-grant proceedings has declined slightly after rising significantly each year since their inception. Presumably, accused infringers are chilled, waiting to

learn if the proceedings are constitutional before initiating them, whenever possible. But those numbers only tell part of the picture. Many of the district court cases that have not been filed are those that would have been filed by the smash and grab-type patent trolls, looking for a quick, relatively small payday without any willingness to litigate. Patent disputes between competitors are growing and are being handled across more complex sets of tribunals – district courts, the International Trade Commission (ITC), the Patent Office and foreign courts.

Broyles: Although patent cases overall have not seen an increase this year, companies continue to pursue patent infringement claims against competitors, particularly in the consumer products space and for the technologies most crucial to their businesses. Global competition continues to be the most common cause of conflict. What has continued to increase at a steady pace is for patent disputes related to key technologies to be the subject of multijurisdictional disputes, with patent battles being fought in multiple countries at the same time. A coordinated approach among a company's counsel around the world will ensure a consistent strategy and increase the chances of an efficient and positive outcome.

FW: Have there been any legal or regulatory developments which have had a particularly significant impact on patent disputes?

Broyles: In the wake of the US Supreme Court's decision in *TC Heartland* earlier this year, there has been a significant increase in the number of motions to transfer on the basis of improper venue. While it still remains to be seen how district courts and the Federal Circuit Court of Appeals will develop the law around what it means to have a "regular and established place of business" for the purposes of venue in patent cases, this will be a heavily litigated issue for years to come. In recognition of this, patent plaintiffs are taking greater care in evaluating the propriety of patent venue

and, as a result, patent infringement cases are being filed in a wider variety of district courts.

Nemec: No issue has been more thoroughly discussed in recent years, and no commentary of this sort would be complete without mention of the Supreme Court's *Alice* decision concerning patentable subject matter. *Alice* and the lower court cases interpreting it have left thousands of issued patents dead on arrival, and have virtually closed the taps for issuance of new software and business method patents. *Alice* has also changed the face of patent litigation by creating a legal basis for courts to invalidate patents at the very outset of a case, before any discovery has taken place. One of the most daunting aspects of patent litigation for an accused infringer is the long and costly discovery process, which, in most courts, would have to be completed before motions to dismiss would be entertained.

Knowles: In the US, there has been a dramatic change in the law on the scope of patent eligible subject matter, resulting in a narrowing of the kinds of innovation companies can receive patents on. Through a series of Supreme Court and appellate decisions starting with the *Bilski* decision in 2010 through the denial of certiorari of *Ariosa v. Sequenom* in 2016, the US Supreme Court has significantly rolled back patent protection on software, business methods, personal diagnostics and genetic products. We are seeing more lawsuits and patent challenges filed to invalidate patents on the basis of ineligible subject matter. We have also seen a trend in courts to determine whether a patent meets this newly constricted patent eligibility standard at the initial pleading stage, instead of providing a full court trial.

Cross: In the UK, the success of the Intellectual Property Enterprise Court (IPEC) and the Shorter/Flexible Trials Scheme in the Patents Court, have made patent litigation more cost effective and accessible. This has led to an increased workload for the courts, so that some cases are taking longer to get to trial.

“THE *TC HEARTLAND* DECISION IS ONE OF THE BIGGEST GAME CHANGING DEVELOPMENTS OF THE PAST SEVERAL YEARS, EVEN THOUGH IT HAS NO DIRECT IMPACT ON SUBSTANTIVE PATENT LAW.”

DOUGLAS R. NEMEC

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Insogna: In healthcare, the BCPIA has had an impact, much as the Hatch-Waxman Act did when it first became effective in the mid-1980s. In fact, the early litigation under the BCPIA is reminiscent of the early Hatch-Waxman cases, as the bench and bar attempt to interpret the provisions of the Act. In the area of licensing and patent litigation settlements, the Department of Justice and the Federal Trade Commission issued updated antitrust guidelines for the licensing of intellectual property in January 2017.

Donoghue: The Supreme Court's *TC Heartland* patent venue decision this summer has already been a sea change. The Supreme Court brought patent venue in line with other types of litigation. Now a defendant can only be sued in its state of incorporation and where it has an established place of business and where significant acts of alleged infringement occurred. Since the suit, case filings in the Eastern District of Texas have dropped precipitously, while filings in the District of Delaware, the Northern District of California and the Northern District of Illinois are up significantly.

Collier: *TC Heartland* is the most significant legal development of the past year. Over the past couple of decades, certain districts, such as the Eastern

District of Texas, have gained substantial experience litigating patent disputes and litigants have become familiar with how to litigate patent disputes in those jurisdictions. One likely consequence of *TC Heartland* is that patent litigation will become more dispersed and less focused in a limited number of jurisdictions. As courts with less familiarity with patent disputes will be called upon to handle them, it raises the potential for more uncertainty and inconsistency with how cases will be handled.

FW: Could you outline any recent examples of court cases and judgments with important implications for the patent dispute arena?

Nemec: The *TC Heartland* decision is one of the biggest game changing developments of the past several years, even though it has no direct impact on substantive patent law. The change in venue law will make it more difficult for patent owners to opportunistically sue in jurisdictions perceived to favour plaintiffs or to return large verdicts. The cottage industry in patent litigation in such jurisdictions will decline. In turn, a greater measure of rationality will return to the patent litigation risk and reward analysis. In the few months following the decision, there is already a sense that the perception of

patents as a vehicle for economic growth is recovering and the notion that patents are a drain on the system may be on the wane.

Knowles: In June 2017, the US Supreme Court granted certiorari in *Oil States vs. Greene's Energy Group*, to address the question whether IPR at the PTAB violates the US Constitution by extinguishing private property rights without a full trial in federal court. The case raises the esoteric issue of whether a patent right is a private property right or a public right granted by an administrative agency. A ruling that a US patent is a private property right would mean that a patent cannot be cancelled without due process in a federal court when challenged.

Cross: In the UK, the Supreme Court decision in *Actavis v. Eli Lilly* has rewritten the test for infringement by bringing in a doctrine of equivalents. This could lead to more patentee-friendly outcomes, but also more uncertainty, and therefore a greater likelihood of disputes going to court rather than being settled. There have also been major decisions in *Unwired Planet v. Huawei*, in which the Patents Court granted a final injunction under a standards-essential patent, and determined how a fair, reasonable and non-discriminatory (FRAND) rate should be determined. Leave to appeal has been

granted, so we should see more on these important issues.

Insogna: The Supreme Court's *Halo* and *Stryker* decisions of June 2016 have important implications. By eliminating the objective recklessness requirement, relaxing the standard of proof to a preponderance of the evidence and eliminating *de novo* review on appeal, the decisions lowered the bar to wilfulness findings. Other important cases include *TC Heartland*, a May 2017 Supreme court case involving the patent venue statute that is already driving down the number of patent case filings in the Eastern District of Texas; *Impression Products v. Lexmark*, a May 2017 Supreme Court ruling that expanded the doctrine of patent exhaustion to encompass all sales inside and outside the US, irrespective of contractual sales restrictions; and *Sandoz v. Amgen*, in which the Supreme Court held in June 2017 that biosimilar makers may give notice of marketing under the BCPIA prior to being licensed by the US FDA.

Reisman: The US Supreme Court's recent grant of certiorari in *Oil States Energy Services v. Greene's Energy Group* has created uncertainty regarding the value and the availability of IPR challenges. In its grant of certiorari, the Court raised the question of whether the IPR system "violates the Constitution by extinguishing

private property rights through a non-Article III forum without a jury". By simply raising this question, the Court complicated litigation strategies and provided a rationale for district courts to deny stays pending PTAB decisions in IPR challenges. Moreover, if the Supreme Court were to conclude that the IPR system is unconstitutional, pending IPR challenges would most likely be dismissed and prior board decisions that revoked issued patents would be called into question.

Donoghue: The Supreme Court has created the biggest patent trends over the last year. In *TC Heartland*, it narrowed patent venue requiring defendants to be sued where they legitimately transact business. In *SCA Hygiene*, the Court held that, like with copyright, there was no laches in patents, although equitable estoppel remains. And the Court strengthened principles of patent exhaustion in *Lexmark*, holding that post-sale patent restrictions could only sound in contract. And while it has not been decided yet, in *Oil States* the Court agreed to consider whether patent office post-grant proceedings are constitutional. While each of the Supreme Court cases altered the patent landscape, if *Oil States* holds IPR and other patent office PGR unconstitutional, it would be the biggest patent law change in the last decade.

Collier: The Supreme Court's decision in *Water Splash v. Menon* represents another important development. In *Water Splash*, a US company – Water Splash – filed suit against a former employee in Texas state court, for unfair competition and related claims. At this time, the former employee – Menon – was living in Canada, so Water Splash served process on Menon by mail. Menon failed to respond, and the trial court entered judgment for Water Splash. Menon appealed, and had the ruling overturned on grounds of improper service. Serving process abroad is governed by the Hague Service Convention, as it is colloquially known, which requires Member States to set up central authorities to receive and transmit service to their nationals.

PATENT DISPUTES ARE OFTEN BASED ON FUNDAMENTAL DISAGREEMENTS BETWEEN THE PARTIES ON THE SCOPE AND VALIDITY OF THE PATENT WHICH MAKES THESE CASES MORE DIFFICULT TO SETTLE.

JAMES CROSS
Maucher Jenkins

Broyles: In addition to the *TC Heartland* decision, there is another case in the US that is receiving a lot of attention and has the potential to impact the entire patent PGR programme, including IPRs and covered business method reviews. This summer, the Supreme Court granted writ of certiorari in *Oil States vs. Greene's Energy Group*, agreeing to consider this question: "Whether inter partes review—an adversarial process used by the Patent and Trademark Office (PTO) to analyse the validity of existing patents—violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury". The court's consideration of this question indicates a possibility that the entire post-grant programme may be held unconstitutional.

FW: If a patent infringement is detected, what initial steps should companies take to resolve the matter?

Cross: Litigation can be expensive and disruptive to all parties, so it makes sense to try to resolve patent disputes without recourse to litigation, and UK courts can penalise parties who fail to do so. Patent disputes are often based on fundamental disagreements between the parties on the scope and validity of the patent, particularly on obviousness, which makes these cases more difficult to settle. It makes sense to get legal advice on these issues as early as possible, and to engage an expert before contemplating litigation.

Insogna: In order to achieve a favourable resolution, it is important to understand the strengths and weaknesses of your case, as well as the business issues surrounding a potential resolution. Gaining this understanding requires a detailed analysis of the suspected infringer's products and activities in the market, preparation of detailed and not overreaching claim charts, due diligence into the validity of the patent and an assessment of the nature of any past business dealings and relative market positions. Before reaching out to the suspected infringer, it is wise to think through the infringer's potential resistance and to be prepared for all arguments. The

A RULING THAT A US PATENT IS A PRIVATE PROPERTY RIGHT WOULD MEAN THAT A PATENT CANNOT BE CANCELLED WITHOUT DUE PROCESS IN A FEDERAL COURT WHEN CHALLENGED.

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patent holder will need to be ready for litigation should the dispute not be resolved in the desired time frame.

Collier: Companies today have an increasing understanding of patent dispute strategies, but may neglect the business impact of implementing them. Accordingly, when developing a patent dispute strategy, it is important to involve the right balance of legal and business personnel to ensure the most effective strategy is developed and implemented. For example, alternative dispute resolution (ADR) in its various forms, such as mediation, early neutral evaluation and arbitration, is firmly established as a mechanism for patent dispute resolution. Although an ADR mechanism will generally be faster and less expensive than traditional litigation, whether it is the best way for resolving a patent dispute depends on evaluating all the legal and business goals that the company has.

Broyles: The initial steps in a patent dispute can have major consequences on the outcome of the dispute. For instance, in the US, unless conducted with care, early communications with a suspected infringer may provide standing for the accused infringer to bring a declaratory judgment action in the forum of its choosing. As another example, the UK has a statutory

framework governing demand letters that must be carefully navigated. Likewise, statements about the scope or value of the patented technology can be used against a patent owner during later phases of the dispute. For these reasons, it is important to conduct early settlement discussions under a confidentiality agreement to protect statements from being used against the company during any future litigation.

Donoghue: Resolving patent disputes quickly and rationally requires understanding and communication. First, you must investigate the claims, whether you are the patent holder or the accused infringer. That investigation leads to an understanding of both your legal positions and the implications to your business. Once you know that, the business team and the lawyers must communicate to understand your goals for the litigation and what, if any, strategic advantage you may derive from the case. Then, having crystallised your position, you need to communicate with your opponent. Of course, doing so without knowing your goals rarely leads to a resolution.

Reisman: Companies wishing to avoid infringement suits should regularly monitor their competitors' patent portfolios. Doing so will allow them to anticipate infringement issues before they arise and

to more fully consider design-around strategies. If an infringement issue arises, these companies should conduct probing claim construction analyses, including a review of the relevant patents' prosecution histories. Such an analysis will allow them to determine the scope of the patent claims and the potential reach of coverage under the doctrine of equivalents.

Knowles: If the company is the patentee, the company should first review its issued patent to closely evaluate whether a court would likely uphold and enforce the patent in litigation. If so, it is good strategy to line up outside counsel, experts and consultants before making a move. Thereafter, the company should evaluate whether to approach the infringing company and start a conversation, and how to do so, or whether to sue first and then talk. An approach to an infringing company could provide the grounds for the infringer to sue first for a declaratory judgement, potentially giving the infringer the advantage of choice of forum and timing. An alternative approach is to file a complaint but not serve it, and then approach the infringer.

Nemec: Step one should be to understand the impact of the infringement on your business. Is a significant competitor knocking off a lucrative product and

threatening to take away your market share or forever erode the prices you are charging for your products? Is the patent at issue one you have licensed to others, or one that you are not actually practising? The answers to these questions will inform the types of relief to which you may be entitled if you are able to prove up the infringement, and hence dictate the course you should follow.

FW: In the US, can you explain the practical benefits that the inter partes review (IPR) process has brought to patent dispute resolution?

Donoghue: The IPR process has helped rationalise US patent dispute resolution. The cost of an IPR, on the order of \$300,000 in legal fees over 18 months, is significantly lower than a \$1m-plus district court litigation. That has had numerous positive benefits. First, patent holders, particularly non-practicing entities, have been forced to lower their settlement demands and expectations to fit in line with the cost of invalidating their patents in IPR proceedings. Second, accused infringers have become more able to challenge patents that they believe to be invalid because of the reduced cost and complexity of IPRs. Third, while district court litigation remains expensive, IPR proceedings have significantly reduced the overall cost of the

typical district court litigation by altering its life cycle.

Broyles: IPRs in at least some ways have been successful in achieving the benefits intended when the AIA was passed: "providing a more efficient system for challenging patents that should not have issued". For defendants, the process has, in fact, brought a relatively quick and inexpensive route to a determination of the validity of patents. For patent owners, on the other hand, IPRs often give them a more objective view of the validity of the patent they have asserted in litigation. Further, because litigation is often stayed during an IPR, companies through the IPR process can save or defer much of the expense of discovery associated with US litigation.

Reisman: The IPR process was designed to provide a mechanism for adjudicating the patentability or validity of an issued patent. This process was to be relatively inexpensive and quick compared to district court litigation. The IPR process is particularly well-suited to challenging a patent for which a single prior art reference, or a simple combination of references, supports the invalidity position, but that reference was not considered by, or was misunderstood by, the examiner during the original prosecution. By limiting the availability of costly and time-consuming discovery, and by focusing on select issues of invalidity based only on the prior art, Congress streamlined the IPR process and made it less expensive than district court litigation.

Knowles: The practical benefit to IPR is realised by potential infringers, who can eliminate patents in their way using an easier, faster process than federal court with a higher chance of success. Because patents challenged in an IPR are not subject to a presumption of validity, an accused infringer need not meet the heightened burden of proving invalidity by clear and convincing evidence. Further, claim construction in an IPR is based on a term's broadest reasonable interpretation, rather than the traditional

“BY LIMITING THE AVAILABILITY OF COSTLY AND TIME-CONSUMING DISCOVERY CONGRESS STREAMLINED THE IPR PROCESS AND MADE IT LESS EXPENSIVE THAN DISTRICT COURT LITIGATION.”

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claim construction standard applied in the courts under *Phillips v. AWH Corp.* While broadest reasonable interpretation (BRI) is also the standard used during initial patent examination to prevent unduly broad of claim scope, an applicant has ample opportunity to amend claims to address rejections during prosecution.

Collier: Over the last six years, IPR proceedings have become a prominent tool for those accused of patent infringement, with broad reporting of their perceived success in invalidating patents. IPR proceedings are known for providing faster resolution at a reduced cost over traditional litigation for evaluating patent validity. IPRs, however, may not guarantee success in the way that was initially perceived. The success rate for invalidating patents in IPRs appears to have declined from initial statistics, and the risks associated with an unsuccessful IPR proceeding are becoming more apparent. For example, where a patent survives an IPR proceeding, the accused infringer is likely left with fewer patent invalidity defences in the district court action and faces a patent that will be perceived as battle hardened. Some courts have allowed testimony regarding the patent office's denial of an IPR petition and this will perhaps only increase in the post-*Halo* world, as evidence proffered to demonstrate wilfulness.

Nemec: The IPR process came to us as part of the AIA in 2012, the result of a long deliberation over patent reform, and aimed at the dual purpose of greater harmonisation with patent systems outside the US and combating perceived abusive patent litigation. The AIA, and the IPR process in particular, has moved the needle at least somewhat on both fronts. IPRs allow anyone, regardless of whether they have been threatened with a patent suit or not, to ask the PTO to take another look at an issued patent to consider whether the claims are patentable over prior art patents and printed publications.

Insogna: The IPR process is a less costly and faster mechanism for adjudication of patentability than district court

“THE SUCCESS RATE FOR INVALIDATING PATENTS IN IPRs APPEARS TO HAVE DECLINED FROM INITIAL STATISTICS, AND THE RISKS ASSOCIATED WITH AN UNSUCCESSFUL IPR PROCEEDING ARE BECOMING MORE APPARENT.”

PAUL COLLIER
Kirkland & Ellis LLP

litigation. The rates of unpatentability findings are relatively high, particularly for instituted IPRs, though the trends are somewhat industry specific. And, the Federal Circuit has high rates of affirmance of unpatentability findings. All of this gives a degree of certainty to an IPR proceeding that is not available in district court, where there are many more issues to be adjudicated and statistics are less meaningful. These benefits are more applicable to challengers than patent owners. Patent owners tend to have more at stake in an IPR compared to a dispute that does not involve an IPR, and are thus motivated to come to the negotiating table earlier. However, if a patent has withstood an IPR challenge, the accused infringer will have a greater incentive to resolve the dispute as compared to a district court case where the validity of the patent is untested.

FW: In Europe, what have been the most notable developments in terms of protecting and enforcing patents? How confident are you that the UPC will succeed, for example?

Knowles: The most dramatic change on the horizon is the advent of the Unitary Patent, which is currently parked waiting for the German Constitutional Court to decide whether the underlying agreements are constitutional. While everyone expected

Brexit to lead to a significant delay, the UK government is still keen to join the UP/UPC system, so apparently not the hold-up. The UP and corresponding Unified Patent Court will be quite powerful when implemented, because of the sheer size of all of Europe. There is also significant discussion around when Supplementary Protection Certificates can be issued to extend the patent term on biopharmaceutical products subject to regulatory review, and what kind of patents are eligible for extension.

Insogna: The implementation of the UPC will significantly affect patent litigation strategy, both in Europe and globally. However, the start of the new system has slipped again, and with Brexit and the recent constitutional challenge against the UPC in Germany, there are some doubts again about its future. In the meantime, patent litigation continues country by country. In life sciences, there have been important case law developments across much of Europe relating to “second medical use” patents. Though this area is still developing, it appears to be developing more favourably toward branded companies, or originators, in Europe, compared to the US.

Cross: Apart from the Unitary Patent, the other main issue has been the likely effect of Brexit. While European patents

will still be able to cover the UK, it is still unclear how Brexit will affect EU trademarks and designs. For example, will existing rights still have effect in the UK post-Brexit, and will it become necessary to apply for national UK rights in parallel with EU rights? Of particular interest to UK-based practitioners is whether they will be able to file for EU rights, although many firms already have offices within other EU countries, or plan to set them up. Much of this will depend on whether the UK remains within the single market.

FW: In your opinion, how important is it to develop a quick and decisive strategy for resolving patent disputes? Are companies paying enough attention to dispute prevention strategies?

Reisman: Companies should commit greater resources to dispute avoidance, as patent litigation in the US is almost always disruptive to the business and will usually interfere with ongoing research and development efforts. Thus, instead of simply readying its own patent portfolio to ensure that the company's key products are covered, a company should also monitor its competitors' marketed and in-development products. Effort should be made to also cover those products. Patents and even pending applications that cover a competitor's products may provide a basis

for cross-licensing arrangements, and thus increase the chances that an otherwise costly and disruptive patent dispute can be settled on acceptable terms.

Broyles: A quick and decisive strategy to resolve the dispute is not only important to achieving a company's goals, but enables them to do so as efficiently as possible. At the outset, a company should ensure that all of its internal stakeholders agree on the company's goals related to the dispute, including the best case outcome in the dispute and acceptable alternative outcomes. Armed with this insight, legal counsel can develop a tailored approach and employ creative strategies designed to achieve those goals.

Knowles: It is good practice to carry out regular searches for patent filings by third parties that may broadly or narrowly cover the company's product. If a relevant third-party filing is identified, the company should authorise an investigation of the validity, scope and enforceability of the patent, as well as what countries it is filed in. It may be important to seek a written opinion of counsel that the third-party patent is invalid or not infringed. A holistic global litigation strategy may also be important, if the company has a global market.

Insogna: For companies susceptible to competitor patent litigation, a quick and decisive strategy is vital. You do not want to be caught flat-footed and risk disruption to your business that could have been minimised or prevented. Adequate preparation is industry specific. In some industries, it is critical to develop a sound IP strategy for the product pre-launch. In others, a detailed strategy for prospective litigation is difficult, because the strategy may change, depending upon the asserted patents, assertion entity, the accused products and other factors. In these industries, once a suit is filed, it is important to fully evaluate the merits of the case and its potential impact on the company to develop a sound strategy for reaching a favourable outcome. Whether a particular company is paying close attention to dispute prevention varies, depending on its stage of growth, its market position and its past experiences with patent disputes.

Collier: While developing a strategy early in the dispute is important, it is equally important to remain adaptable as circumstances change. A quick, decisive strategy could be detrimental if unyielding adherence to it leads to a refusal to recognise new opportunities for resolution. Since every patent dispute is unique, companies must understand what tools are available, and have the flexibility to implement different strategies to address the unique circumstances presented by a given dispute. In doing so, integration of business and legal personnel is critical. ADR mechanisms can be the best strategies for resolving some disputes, and should always be considered.

Nemec: I believe strongly in the need for quick and decisive action in the face of a patent dispute. With rare exceptions, there is no upside to delaying or ignoring a patent infringement issue, whether it be an active infringement of one's rights or a threatened suit. But advance preparation should have less to do with developing a formulaic strategy for responding to patent infringement situations, and more to do with selecting a pool of professionals who understand a company's business and can

“WHETHER A PARTICULAR COMPANY IS PAYING CLOSE ATTENTION TO DISPUTE PREVENTION VARIES, DEPENDING ON ITS STAGE OF GROWTH, ITS MARKET POSITION AND ITS PAST EXPERIENCES WITH PATENT DISPUTES.”

ANTHONY M. INSOGNA
Jones Day

swiftly propose a response to whatever situation happens to arise.

Cross: For patent holders, the early detection of potential infringements is essential. It is much easier to deter potential infringers before they have committed significant resources to their project. On the defensive side, most companies have no policy of checking freedom to operate (FTO), choosing instead to deal with intellectual property disputes as they occur. It is important to develop a reasonable and proportionate FTO strategy, aimed at detecting the most serious risks without undue cost or delay.

Donoghue: Sophisticated companies have largely spent significant resources on how to look at and handle patent litigation, including dispute prevention strategies. We see more and more companies adding escalation clauses to agreements, requiring that business principals meet in person, live or by telephone, to discuss patent or indemnification disputes before they are allowed to get to court. That seemingly small change prevents significant amounts of costly litigation from ever being filed.

FW: How important is it to engage expert witnesses in certain types of patent disputes – and why?

Reisman: In cases involving medicinal chemistry or biotechnology, expert witnesses often play critical roles. Judges, including the Administrative Patent Law Judges of the Board of Patent Appeals and Interferences (BPAI), often rely on the testimony of these experts in assessing the ordinary meaning of disputed claim terms, identifying the teachings of key prior art references, and understanding the perspective of the hypothetical ‘person of ordinary skill in the art’. These experts should be chosen with great care because academic accolades and an impressive list of peer-reviewed publications do not necessarily make for a convincing expert.

Insogna: Experts are absolutely critical in complex patent disputes in district courts and in the ITC. The same is true

SOPHISTICATED COMPANIES HAVE LARGELY SPENT SIGNIFICANT RESOURCES ON HOW TO LOOK AT AND HANDLE PATENT LITIGATION, INCLUDING DISPUTE PREVENTION STRATEGIES.

R. DAVID DONOGHUE
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for IPRs. A good expert witness will help the lawyer develop the strongest case that can be developed on the facts, and will help the PTAB, judge or jury to understand the merits of the parties’ case, and why their opponent’s case involves a mistaken understanding of the technology or the particular technical facts involved.

Knowles: Technical experts are useful, and sometimes required, in complex patent matters. During the evaluation period, an expert may be used to provide in-depth factual information about a market or area of science or technology at a specific relevant point in time. Since the validity of patents are evaluated based on their priority dates, it is sometimes necessary to identify an expert who was active in the area at that time. In the US, the obviousness of an invention is measured with reference to ‘the person of ordinary skill in the art’ – a hypothetical person assumed to be aware of all public information as of the critical date. A technical expert can assist in clarifying who the person of skill in the art was, what his understanding would be of the prior art, and the differences between the prior art and the claimed invention.

Nemec: In patent infringement lawsuits and contested Patent Office proceedings, it is hard to imagine not engaging expert

witnesses – your opponent surely will have experts and without a competing opinion before the fact finder you may be taking a serious risk. The closer question is whether it is necessary to retain experts at the very outset of a dispute. If cost restraints are taken out of the equation, however, the answer becomes an easy ‘yes’.

Collier: Expert witnesses, both technical and damages experts, are usually indispensable to a patent dispute. If hired early in the litigation process, technical experts can provide invaluable guidance to assess the strengths and weaknesses of patent infringement and invalidity positions and help prepare the trial themes and theories to develop during the case. Some question the value of expert witnesses, arguing that they cancel each other out where there is a ‘battle of the experts’, but this is a dangerous philosophy. For a jury, a well-prepared and qualified expert can present a voice they can trust to understand and interpret the technology, which can be the difference between a favourable and unfavourable verdict. The timing of hiring an expert witness is also important. Although some litigants may have a cost-motivated desire to retain experts as late as possible in a dispute, an expert’s advice early in a dispute can often save money by setting a litigation on the right footing initially.

Cross: Expert witnesses are almost always required in UK patent litigation, and their evidence is essential on subjective issues, such as interpretation of the claims, and obviousness. Cases are often won or lost on the strength of the expert evidence. UK patent litigation is very front-loaded. Parties need to put forward their case early in proceedings; their expert evidence should support that case, so it is essential to engage an expert as early as possible.

Donoghue: While expert witnesses are typically required in patent litigation to explain complex technologies to judge and jury, in the most complex technologies having an expert early in the process is even more critical. And the need for experts is even more acute where your in-house technical team has a narrower, industry-focused view of the technology or is not well-versed in the asserted patent's technology space. An outside expert can quickly identify prior art, help to see claim construction issues at the outset that you might otherwise miss and identify critical indefiniteness issues. Additionally, in IPRs, the petitioner is required to present any expert testimony in its initial position. So, if you do not retain an expert at the outset, you will not be able to use one later in the IPR.

Broyles: Expert witnesses are crucial in patent cases – both for the technical issues of infringement and invalidity, as well as an economic expert for damages issues. A technical expert with specialised experience and education in the relevant technology area can provide invaluable insight and resources that help craft winning arguments from the outset of a case. Therefore, it can be helpful to identify and engage technical experts early on during the development and evaluation of the interpretation of the patent claims, infringement and validity. Early involvement by an expert also provides a chance to evaluate the expert prior to the time for designating testifying experts, to ensure that the expert is a good fit for your case.

FW: What key piece of advice would you give to companies on effectively protecting their patents and enforcing their rights? What are the essential elements of an ongoing monitoring and detection process, for example?

Insogna: We encourage companies to regularly evaluate and re-evaluate their existing and anticipated patent portfolio in light of what is happening with their competitors to ensure that they have a sound strategy behind their patent portfolio, for both offensive and defensive purposes. Thus, keeping an eye on

competitors and market developments is essential to any monitoring and detection programme.

Knowles: The first and most important requirement is that the management of an innovator company be fully committed to the importance of patent protection to the value of the company. Good corporate governance of an innovator company requires the establishment of a framework in which researchers are encouraged to invent, the company has senior level experienced patent counsel guiding it, and there is established and consistent communication between management, patent counsel, general counsel and regulatory counsel, if applicable. Management should continually check in with this framework of people to make sure it is functioning at top efficiency, and should be asking probing questions. Management should also implement a rigorous policy pertaining to corporate documents, notebooks and emails, with a document retention and destruction policy that is updated routinely to comply with the latest legal requirements.

Nemec: A company seeking patents with an eye toward protecting an exclusive product market, such as in the pharma industry or to monetise the patents through litigation or licensing, should be careful in its selection and management of patent prosecution attorneys and agents. First, avoid being pennywise and pound foolish. Companies with a high volume of patent applications will often negotiate bulk rates or flat fees per application. Second, while there is no obligation to perform an exhaustive prior art search before seeking a patent in the US, if the expectation is that you may enforce a given patent, there is merit to performing a search and taking care to avoid the prior art at the outset. Finally, consider enlisting the services of a patent litigator to review important patent applications prior to issuance to offer a view on the strength of the claims.

Broyles: A company that is serious about protecting its intellectual property rights should be leveraging its internal

“WE WILL CONTINUE TO SEE STEADY ACTIVITY IN COMPETITOR LITIGATION, PARTICULARLY IN THE CONSUMER PRODUCTS SPACE.”

KEITH E. BROYLES
Alston & Bird LLP

resources to identify competitor products that may run afoul of the company's intellectual property through monitoring and mapping patents to competitors' products. This should be done under the legal department's control and oversight. Employee training is an essential element of any such detection process. For example, all company employees should have some basic internal training in protecting the company and its intellectual property. Employees should also be trained on careful communication about intellectual property matters, legal doctrines to protect their communications about intellectual property matters, and when to involve the company's legal department.

Cross: Companies need to develop a protection and enforcement strategy for all their IP, including patents. The strategy should be reviewed regularly as the company and its competitive landscape changes, but should be adhered to. Patents in particular are a long-term investment. Too often, we see 'boom and bust' patent filing programmes, where a company files a large number of patents one year, perhaps in response to being sued by a competitor, only to abandon them in subsequent years in the face of budgetary pressure.

Donoghue: The key to a good enforcement programme is making it systemic and tapping into the resources of your employees. Employees are the eyes and ears of the company in the marketplace. Your sales force sees what your competitors are doing, at least through the lens of your customers, if not directly. You need to teach them to watch for infringement or potential infringement of key intellectual property. They will see it first and if they are taught to watch for it and report it, you may be able to seek early injunctive relief to stop an infringer from taking market share.

Collier: One key point is that companies should ensure that their patent portfolio strategy aligns with and supports their core business and technical strategy. Stated differently, companies should prioritise pursuing patents that cover the technical areas and innovations they are pursuing.

Not all patents carry the same value, and where corporate legal departments are often dealing with finite resources, companies should focus on those that matter most.

Reisman: Enforcing a patent in the US almost always disrupts the patentee's business and interferes with its ongoing research and development efforts. Patent enforcement should be viewed as one of several tools at a company's disposal, and should only be pursued from a position of strength and with the company's business goals firmly in mind. A company should ensure that those prosecuting its patent portfolio work in tandem. For example, any prior art references identified against part of the portfolio should be evaluated across the entire portfolio and, if necessary, patentability positions and prosecution strategies should be refined.

FW: What are your predictions for patent dispute activity over the coming months? What types of disputes do you expect to dominate this space?

Donoghue: We expect to see patent disputes continue to rise, including more district court litigations, particularly among competitors. With almost four years of decisions outlining what is and is not patentable software since the Supreme Court's 2014 *Alice* decision, patent holders seem to be filing fewer cases on bad software patents, although there are still a fair number filed. And while we think the Supreme Court likely holds that IPRs are constitutional, if it holds them unconstitutional the patent world will be plunged back into the pre-AIA world of runaway district court litigation at a significant cost to businesses with no real upside to anyone but patent holders.

Nemec: The past few years – arguably the past decade or more – have been hard times for patents in the US. Some trace the trigger to the Supreme Court's decision in *eBay v. MercExchange* which eliminated automatic injunctions in patent cases. Others blame the proliferation of 'patent trolls'. Whatever the cause, patents and the patent system have been under constant

attack, and public and industry perception of the value of patents has been seriously tarnished. But we are nearing the end of the negative cycle, and the *TC Heartland* decision may be the shot of adrenaline that the patent system needed.

Collier: One area that presents the potential for patent and other legal disputes is autonomous driving, as we have seen with recent high-profile trade secret disputes. Several prominent companies are developing the technology to drive this field forward, and as this technology goes from the drawing board to commercialisation, the prospect of high-stake patent disputes developing is high.

Cross: If the Unified Patent Court does open in 2018, we could see a raft of centralised revocation actions, similar to the IPR activity seen in the US. Conversely, we could see a drop-off in the number of EPO oppositions, as the option of centralised revocation will remain after the nine month opposition window closes, at least for patents that have not been opted out. We could also see an increase in threatened or actual litigation by patent licensing companies, using the threat of a near EU-wide injunction to force more advantageous settlements.

Reisman: At the Court of Appeals for the Federal Circuit, the interplay of the doctrine of inherency and the law of obviousness will continue to develop. Over the last few years, in cases such as *Kao and Par v. TWI*, the Federal Circuit signalled that doctrine of inherency was not limited to the law of anticipation, and could also play a role in the law of obviousness. Two recent decisions from the Court of Appeals for the Federal Circuit – *Millennium Pharma v. Sandoz* and *Honeywell v. Mexichem* – show that the court is grappling with the proper role that the doctrine of inherency should play.

Broyles: We will continue to see steady activity in competitor litigation, particularly in the consumer products space. We can also expect investigations before the ITC to continue to be a popular option for

competitor litigation. Also, many indicators point to even fewer filings by non-practicing entities, including the viability of PGRS as a vehicle for invalidating patents, the post-*Alice* law on Section 101, the lowered standard for obtaining fee awards in the US and the articulation of the venue standard in *TC Heartland*.

Knowles: In the US, I expect more administrative litigation by potential infringers at the PTAB, more court litigation to clarify the metes and bounds of the Supreme Court patent eligibility case law and activity by trade organisations to introduce bills in Congress to overturn or modify some of these recent Supreme Court decisions. In Europe, we are all anticipating the arrival of the UP and the UPC.

Insogna: There is a tremendous amount of activity in both the high tech and life sciences sectors, including 3D printing, solar cells, sensor and software technologies associated with the push toward autonomous vehicles, AI, virtual and assisted reality, the Internet of Things (IoT) ecosystem, the blockchain, and new biologics and medical devices. While it is difficult to predict when new technologies will be the subject of patent disputes, these are the subjects we would expect to see emerge in patent litigation. I expect that we will continue to see a substantial number of IPR filings, assuming that the IPR process is not found unconstitutional in *Oil States*. I also expect to see fewer case filings in the Eastern District of Texas as a result of the *TC Heartland* decision, and more cases in Delaware and California, as we have already begun to witness. ■