# A busy patent year in the United States

Three leading attorneys look at developments in the US patent landscape during 2010

By **Joff Wild**

There is rarely a quiet year when it comes to patents in the United States, and 2010 certainly was not one of them. From a series of reforms and new initiatives announced by the US Patent and Trademark Office (USPTO), through major decisions handed down by both the Court of Appeals for the Federal Circuit (CAFC) and the Supreme Court, to the boom in false marking litigation and the growing popularity of the International Trade Commission (ITC), it was a very busy 12 months.

In our annual overview of the US patent landscape, three senior attorneys at the heart of the action – Marshall Gerstein's Paul Craane, W Edward Ramage of Baker, Donelson, Bearman, Caldwell & Berkowitz, and Toni Junell-Herbert from Patton Boggs – give their assessment of recent developments and look forward to what might happen next.

***How would you characterise the current patent environment in the United States?***

***Paul Craane:*** *Constantly evolving, with little assistance from Congress. The US Supreme Court is poised to review at least three patent cases during the present term:* Global-Tech v SEB *(state-of-mind requirement for inducement of infringement);* Stanford v Roche Molecular Systems *(ownership under the Bayh-Dole Act); and* Microsoft v i4i *(standard for a validity challenge in litigation). In addition, the court has asked for further briefing from the US solicitor general on the cert petition in* Applera Corp v Enzo Biochem Inc *(definiteness of claim language), which may signal its willingness to take this case up as well. The Federal Circuit has also recently addressed several cases* en banc *and is scheduled to provide guidance on inequitable conduct* en banc *in the near future. On the administrative front, the USPTO is taking action on a number of issues through a combination of formal rulemaking and informal guidelines. In the meantime, the Patent Reform Act, in and out of committee for the last five years, has been carried over yet another year.*

***W Edward Ramage:*** *Embattled. The USPTO has been struggling with an enormous backlog of cases and quality issues. Addressing these problems will require money and time: money to support the hiring of additional examiners, and time to provide them with training and experience. Yet even today there is a substantial question as to whether the USPTO will receive sufficient funding.*

***Toni-Junell Herbert:*** *The recent economic downturn and correction appear to have created renewed interest and recognition of the importance of intellectual property and its laws to the US economy. As Paul says, we have seen the Supreme Court taking more IP, while the Federal Circuit has also been attempting to rein in damage awards. The courts seem to be judicially addressing some of the concerns previously fuelling the fire of those demanding patent reform. We have also seen a number of positive changes at the USPTO, including the institution of the new count system and pilot programmes for accelerated examinations; although it is too early to gauge their success, they indicate that the USPTO is attempting to deal with its issues and improve the quality of*

*examination while reducing the time to allowance. Thus, from both the administrative and judicial side, it is clear that efforts are being made to strengthen and stabilise our current IP system incrementally, allowing for increased consistency and greater predictability.*

***Would you say that it has improved over the last 12 to 18 months, or worsened?***

***WER:*** *There has been some slight improvement for patent prosecution. The pendency periods have been reduced slightly (or, at least, have stopped growing). However, quality remains a major problem; by quality, I mean the quality of the actions and reasoning of the examiners. In too many cases I am faced with sequential new searches, perhaps caused by a lack of understanding of the invention, and nonsensical interpretations of the prior art. I have seen obviousness rejections based on multiple pieces of prior art strung together simply because a word-based search found that the prior art somewhere used a word also used in the claims, even if in a different context and with a greatly different meaning. While some of this may be due to inexperience, there is undoubtedly also a time restriction element: examiners do not have the time truly to understand the invention and the prior art, and often have to resort to cut-and-paste rejections from other office actions. Ideally, examiners could get to a patent application quicker and spend more time considering it when they do, but that is going to require more examiners, more training and more money for the USPTO.*

*On the litigation side, patent litigation has worsened due to the new crop of patent marking cases. A lot of time and money is being used to defend these cases, which mostly involve no more than negligent oversight of patent expirations.*

***TJH:*** *The overall climate has improved; however, this is not to say that everything has got better. Whether it is because the changes at the USPTO have not been around long enough to have made a significant impact or that more changes are needed, during the last year or so we have seen a definite shift in the chemical and biotech examination core away from the mandate of compact prosecution. Specifically, there has been an increase in weaker first office actions, an increase in examiners' improper handling of declarations and examiners struggling in their application of the Patent Cooperation Treaty rules.*

***PC:*** *This is a hard question to answer, but I believe it would improve if Congress would step up and accept its role as a partner in the formation of US patent law. When the Supreme Court decided* Bilski *this summer, many attorneys faulted the court for not developing a clear set of rules for the patent community to follow. Unfortunately, the judiciary can only develop the law one case at a time, and even then only as to the issues raised by the facts. While the USPTO has some rulemaking powers, and thus can address issues on a more comprehensive, detailed level, there are limits to the USPTO's power, as illustrated in a recent series of high-profile legal challenges to that power. While I may not be a personal fan of every change that is proposed in the present version of the Patent Reform Act, periodic, thoughtful action by the legislative branch is sorely lacking at present.*

***David Kappos has now been the director of the USPTO for a little over a year. What difference has he made?***

***TJH:*** *While it is still too early to tell, it definitely appears that Kappos is working to deal with the issues confronting the USPTO.*

*Since he has taken the position, we have seen implementation of the new count system as well as pilot programmes for accelerated examination. Perhaps as a result, we have also seen more active engagement and phone calls from examiners attempting to advance prosecution.*

***PC:*** *Backlog has long been an issue at the USPTO, as Edward and Toni mentioned. Under the previous director, an attempt was made to force limits on the application and the examination process so as to discourage or even prevent patent application filings. Those rules were challenged in court and ultimately withdrawn by the present administration. Kappos's USPTO has eschewed the stick in favour of the carrot, sponsoring numerous pilot programmes to attempt to encourage applicant behaviour that will reduce the backlog. Kappos has also done a considerable amount to push back the curtain and make the USPTO's inner workings more visible to the patent community. Part and parcel of these changes has been a growing cooperative spirit within the examining corps toward the patent bar and applicants, providing greater opportunities to work with the examiners. My impression is that all of these changes will assist in reducing the backlog, but it will take time for the cultural shift to take root.*

***WER:*** *Kappos has had a moderately successful first year. He has slowly chipped away at the backlog, withdrawn some proposed rules that were receiving a substantial negative reaction, overhauled the patent examiner evaluation process and proposed some innovative ideas,*

*including a three-tier processing proposal to allow some applicants to pay for faster processing. I expect him to continue with his reforms, but it will take a bit of work to overcome the twin problems of agency inertia and funding.*

***How confident are you that the office will achieve Kappos's stated aims of improving the quality of issued patents and cutting the backlog of applications?***

***PC:*** *The director is attempting to implement a cultural change, not a structural or an organisational one. Cultural changes are fundamentally more difficult to achieve, but may provide profound benefits when successful. Of course, problems with examiner hiring and retention could undercut any progress that is made, as may the inability of the USPTO to hire additional administrative patent judges to reduce the sizeable backlog of appeals. While the USPTO is funded completely by user fees, the size of those fees and the annual redirection of those fees by Congress create funding issues that have been tied to the USPTO's hiring and retention difficulties.*

***WER:*** *I am moderately confident that there will be a continued reduction in the backlog. Although it will be relatively minor, at least it is now moving in the right direction. However, I am less confident in seeing a substantial improvement in quality this year. As I mentioned before, I measure quality based on the quality of the actions and reasoning from the examiners, exhibited primarily in their office actions. I would much rather deal with a good, well-reasoned rejection based on clearly applicable prior art, where the examiner and I can then engage in a reasonable dialogue to see whether there is something patentable in the application at hand. That circumstance, unfortunately, is rarer than I would like, and only time and experienced examiners will change that.*

***TJH:*** *I guess my answer would be cautiously optimistic. I am hopeful that since Kappos has put the new count system into effect, his next step will be to overhaul the patent performance system that presently allows end loading by examiners. With end loading, we have a situation where some examiners do the majority of their actions and work at the end of the quarter. This is resulting in shoddy office actions and costly prosecution. The combination of the new count system with elimination of this end loading should increase the quality of examination all around. As for the backlog, the new count system appears to be reducing the time for new applications to get a first action.*

***In June 2010 the Supreme Court handed down its long-awaited decision in the In re Bilski case. How has the decision affected owners of business method and software patents?***

***WER:*** *For all the build-up, the Supreme Court's* Bilski *decision has changed little. Most applicants were already preparing specifications and claims to comply with the machine-or-transformation test, and with the USPTO's follow-up guidelines effectively creating a machine-or-transformation test safe harbour, they will continue to do so.*

*This is underscored by the recent Federal Circuit decision in* Prometheus Labs v Mayo Collaborative Services *on remand after* Bilski. *The Federal Circuit had earlier held that a medical testing method was patentable under the machine-or-transformation test because the human body is always transformed followed administration of a drug. The US Supreme Court had granted* certiorari, *vacated and remanded the prior opinion after issuing its* Bilski *decision. A panel of the Federal Circuit has now upheld the prior decision, ruling that* Bilski *did not affect the conclusion that the claims were patentable.*

*In effect, we now appear to have what I call a bright-line syringe or injection test: any method claims that involve the injection of a drug into a subject will always meet the transformation prong of the machine-or-transformation test, and thus will be patentable subject matter.*

***TJH:*** *If nothing else, it has taken away the uncertainty and concern over the patentability of business methods. Now there is no question what the Supreme Court will do; it has determined that business methods are patentable and the parameters are clearer and better defined. The decision has made it much easier for the owners to predict their ability not only to obtain patents, but also to assess the risk associated with enforcement.*

***PC:*** *The real story of* Bilski *probably remains the opinion that wasn't: Justice John Paul Stephens's dissenting opinion. If Justice Stephens had been able to persuade Justice Scalia to sign on to that opinion, business method patents would have been a thing of the past. However, business methods survived to fight another day. Although the court decided that the machine-or-transformation test is not the only test, it remains the only test approved of by the court as "a useful and important clue", and thus it is likely to remain at the centre of*

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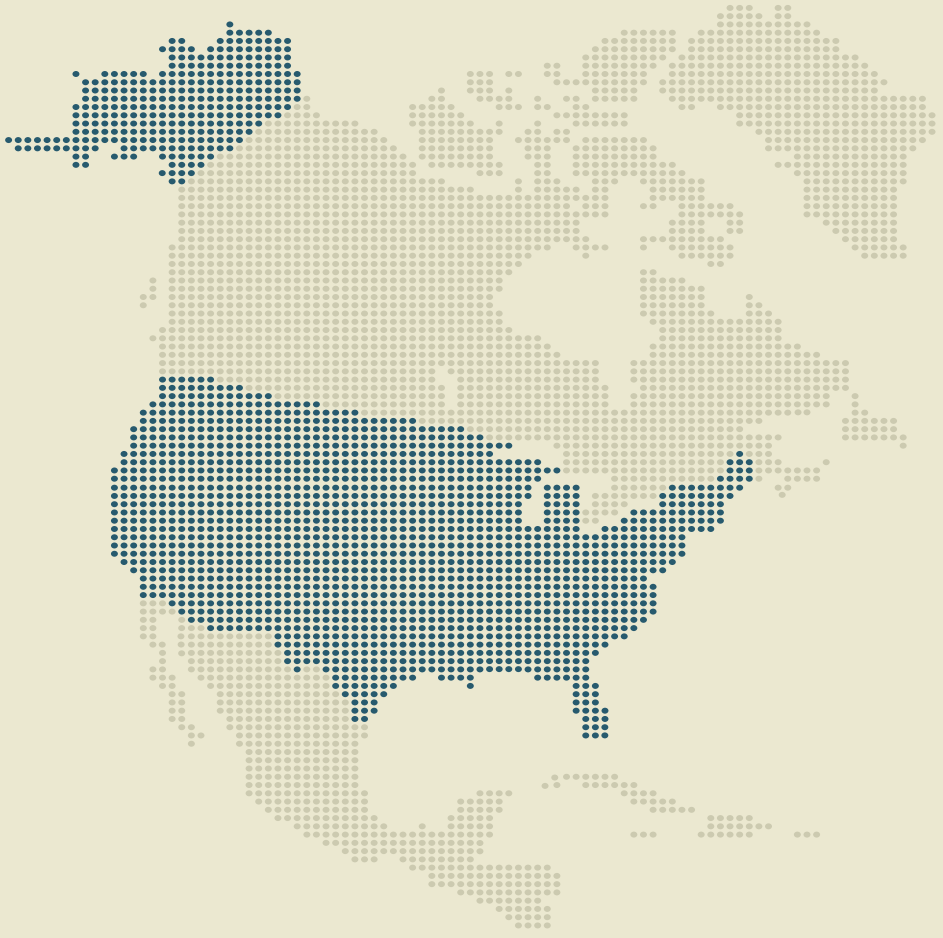
*many such analyses. This fact has been borne out by the USPTO informal guidelines issued in the wake of* Bilski*, in which the machine-or-transformation test plays a pivotal role. Still, I have to disagree with the suggestion that a decision such as* Prometheus Labs v Mayo *underscores that little has changed, given the way in which the Federal Circuit decided patent eligibility without resort to the machine-or-transformation test in* Research Corp Technologies Inc v Microsoft Corp*, deciding the case on principles of "abstractness" instead.*

***The next patent case to get referred to the Supreme Court is* Global-Tech v SEB*, in which the court will determine the level of intent required for inducing infringement. What are the key issues of this case that patent owners should be aware of?***

***TJH:*** *In* Global Tech*, the Supreme Court will be clarifying the legal standard for the state of mind requirement for a claim of active inducement of infringement. The court will essentially be determining whether evidence of an accused inducer's deliberate indifference to the risk of patent infringement will give rise to an inference of purposeful conduct. This case should be of interest to patent owners as it may result in a more practical standard that allows the patentee to assess whether the alleged inducer's state of mind is at the level of culpability.*

***PC:*** Global-Tech *flows from* DSU Medical Corp v JMS Co*, an earlier case decided* en banc *by the Federal Circuit. According to* Global-Tech*,* DSU Medical *held that the accused must* knowingly induce infringement*, and not simply knowingly induce the* acts *that constitute infringement. The accused infringer in* Global-Tech *reasoned that to induce infringement knowingly, the accused must actually know of the patent in suit. Because the accused did not, proof of inducement of infringement was impossible. The Federal Circuit disagreed and held that deliberate disregard for a known risk of a protective patent is sufficient to show knowledge where, as here, the accused copied the patentee's product (perhaps slavishly) and failed to tell its attorney that it had done so. The Federal Circuit particularly distinguished deliberate disregard from a "should have known"*



*standard; that is, the court must look not only at what a reasonable person would have done, but at what this particular accused did. The behaviour of the accused in this case definitely sets off alarm bells, as would actions taken purposely to avoid knowledge of a patent, and so striking the right balance between too narrow and too broad a standard may be difficult when faced with these facts.*

***WER:*** *From the patent owner's perspective, the Supreme Court's decision will determine the extent to which patent holders will be able to use indirect infringement claims as an effective litigation tool. In particular, if the Federal Circuit's ruling is upheld, it may enable a patent holder to reach infringers outside the territorial United States (the infringer in this case was based in Hong Kong, and allegedly manufactured and transferred title to the goods overseas).*

*The issue in* Global-Tech *is: what state of mind is necessary to provide induced infringement under 35 USC 271(b)? The Federal Circuit held that all that is required is "deliberate indifference of a known risk", such as whether a patent exists. The Supreme Court is being urged to require "purposeful, culpable expression and conduct" to encourage an infringement, which presumably would require knowledge of the patent and intent to encourage infringement.*

***The* Bilski *case aside, what do you consider to have been the most important patent cases decided in the US courts over the last 12 months?***

***PC:*** *December 2010 saw the Federal Circuit's first application of* Bilski *in* Research Corp Technologies Inc v Microsoft Corp. *As I mentioned earlier, the court did not attempt to apply the machine-or-transformation test in* RCT, *deciding the case instead on the fundamental issue of "abstractness". Thus, we now have our first suggestions as to how the Federal Circuit will deal with an "abstract idea" challenge to patent eligibility in a case where the patentee prevailed, but may well have failed pre-*Bilski.

*Beyond this recent development,* SiRF Technology Inc v ITC *and* Princo Corp v ITC *are both instructive.* SiRF *underscores the importance of drafting claims so that they are infringed by a single actor, thereby avoiding thorny issues of joint infringement. On the other hand,* Princo *illustrates that while the defence of patent misuse may lie at the intersection of antitrust and patent law, there are certain issues which may give rise to an antitrust cause of action, but will not provide a defence to patent infringement. Finally, for those persons seeking to advise their clients or their companies in both prosecution and litigation matters, I would recommend* In re Deutsche Bank *concerning the appropriate scope of patent prosecution bars in protective orders.*

***WER:*** *In* Pequignot v Solo Cup Co *the Federal Circuit gave patent owner defendants a substantial victory in holding that the liability under the false patent marketing statute requires conscious intent to deceive. This case does not affect patents* per se, *but addresses the flood of new lawsuits based on false marking. Under an obscure provision of the patent law, an entity that incorrectly marks a product as patented (eg, continuing to mark after a patent has expired) can be liable for damages of US$500 for each falsely marked item. The potential liability for many companies is enormous (eg, Pequignot asserted that more than 21.7 billion lids were wrongly marked and sought US$500 per lid in damages).*

*In* Association for Molecular Pathology v USPTO *(the* Myriad Genetics *case), the District Court for the Southern District of New York held that the human gene is not patentable subject matter, invalidating a number of claims in patents held by Myriad Genetics, directed to two genes associated with breast cancer. The decision is on appeal and whether any or all of the decision will survive remains to be seen. The case is important not for whether the district court judge's opinion survives, but because it has brought this issue to the forefront and pushed it to the appellate level. Already we've seen the Department of Justice backtracking in its briefing on the patentability of genes* per se. *Ultimately, I expect this to end up before the Supreme Court.*

***TJH:*** *The* Ariad *case is an interesting one because it clarifies that the written description requirement is alive and has not been subsumed within the enablement and best mode requirements. The case also highlights not only that a written description of the invention is required, but also that the extent of disclosure necessary is proportional to the unpredictability of the science involved.*

*Another interesting case, particularly now that the Supreme Court has agreed to hear the appeal, is* Microsoft v i4i LP. *Here, the court will address whether a lower preponderance of the evidence standard applies to invalidity challenges based on prior art not considered by the USPTO rather than the traditional clear and convincing evidence standard that applies to the USPTO's determination to grant a patent.*

***False marking suits have been making headlines this year. What issues have arisen from recent case law that patent owners need to be aware of?***

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***WER:*** *The false marking cases are designed to bring a quick settlement. While the Federal Circuit in* Solo Cup *raised the bar by requiring conscious intent to deceive for liability, the cost of litigation and the potential for outrageously large damages under the statute create a strong incentive to settle early. However, I believe that the majority of cases involve simple negligence (eg, a patent expiring), and thus the true cost to be considered here is the cost of litigation. A company caught in one of these suits should test the pleadings with motion practice, which often are devoid of any factual allegations supporting an intent to deceive. And all companies with patent products should immediately audit themselves to find and fix any mismarked products or products with expired patent numbers.*

***TJH:*** *Since the Federal Circuit's decision in the* Forest Group *case, the value of these* qui tam *cases is now financially appealing. With statutory damages of US$500 per occurrence, and an occurrence being interpreted to be each product sold with the false marking, significant incentives now exist for plaintiffs to search for a mismarked product. Unsurprisingly, court dockets are now crowded with this type of case. Perhaps aware of this turmoil, the Federal Circuit and district courts around the country have recently been taking a closer look at the intent requirement. Product manufacturers now need to realise that the stakes are high and they need to monitor, police and remove outdated patented markings.*

***PC:*** *I agree with Toni that false marking previously received very little notice and would have remained in the shadows but for the Federal Circuit's decision in December 2009 to permit a penalty of up to US$500 for each mismarked item. Because marking a product with an expired patent may be considered to be false marking, there is a real potential for non-practising entity (NPE) type mischief at the present time, even though* Pequignot v Solo Cup Co *showed that the requisite intent may be difficult to prove and liability may thus be avoided. The potential for ligation has caused many companies to do away with marking altogether, considering the costs of administering such a programme. Of course, there are benefits to leaving off the patent markings other than just managing risk: without the markings, competitors are left without a roadmap as to which patents the manufacturer considers to be protecting the product.*

***How much of a threat are NPEs to operating companies these days and what are the most effective ways of defending against them?***

***TJH:*** *NPEs are no more a threat than any other company with patents that actively monitors and enforces its rights. While at one point the cost of patent litigation may have kept smaller NPEs from filing an enforcement action, today's market has more firms doing contingent litigation, so the cost is no longer such a deterrent. As for the most effective way to deal with them — it is to avoid entanglement with them by doing appropriate patent searching and product clearance at key stages of product development.*

***PC:*** *NPE litigation is not going away. Recent studies suggest that while NPEs are less likely to win than practising entities, their damages awards are on average triple those won by practising entities since 2001, so the incentive is there to continue to file suit. One significant challenge faced by operating companies has been the ability of the NPE to pull the defendant into a jurisdiction that is particularly well suited to plaintiffs — for example, where the speed of the proceedings would put the alleged infringer at a decided disadvantage in defending itself. Recently, though, the Federal Circuit has been willing to use its* mandamus *power to force a transfer where the ties to the forum jurisdiction are tenuous, such as in* In re Acer America. *Unfortunately, while there may be some improvement in dealing with the* old *NPEs, operating companies must now deal with the* new *NPEs — the false marking NPEs. While legislative action has been proposed to cut off standing to non-competitor false marking litigants, no congressional assistance is on the immediate horizon. As mentioned by the other panellists, rigorous application of heightened pleading requirements is providing some temporary relief from these lawsuits.*

***WER:*** *NPEs generally are a threat only in that they will drain cash from you. My experience has been that they are much more interested in what you are willing to pay to make them go away than in trying to shut you down. My recommendation in most situations is to demonstrate that you are willing to litigate the matter fully and be willing to do so. If the NPE recognises that litigating with you will cost more than the potential payout, or may risk the patent itself, I believe that it will be much more reasonable in dealing with you. You should also consider the potential for re-examination of the patents in question. Filing for re-examination can often derail a lawsuit. In addition, demonstrating that you have good prior art and are prepared to file for re-examination unless the NPE is willing to settle reasonably may result in a quick settlement in some cases.*

***The ITC has been drafted in to investigate several high-profile patent disputes in the last year. How have the role and scope of the ITC evolved in recent years?***

***PC:*** *The ITC is no longer just for US companies. Foreign companies are coming to recognise the advantages of trying their cases there, instead of the federal courts. The ITC combines speed and expertise in patent matters with remedies that can seal the borders to competitors, an especially potent weapon considering the amount of manufacturing that has been shifted offshore in recent years.*

***WER:*** *The ITC has become a fast-track patent enforcement mechanism under its Section 337 authority for some US patent owners, with limitations. If the infringer is importing infringing goods into the United States, a complaint can be lodged with the ITC and you can obtain an import ban much more quickly than in a standard court proceeding. Of course, it only affects imports of goods from other countries and you will not get damages. And you must also show competitive harm, which means that you actually practise in the United States the inventions protected by the patent claims being asserted, and compete with the infringer.*

*The ITC also has Section 337 administrative law judges who focus primarily on patent investigations, so the patent owner can expect more specialised trial-level adjudication than with a district court. More and more companies are becoming aware of the advantages of the ITC route and are using it instead of, or as a parallel proceeding to, standard patent litigation. This trend will continue as international trade in high-tech and similar markets continues to expand in importance.*

***TJH:*** *Over the last five to 10 years, the popularity of the ITC has definitely grown. Ever since the* eBay *decision, the ITC is perceived to offer the advantage of being able to obtain an exclusion order as opposed to the post-*eBay *district court environment, where the perception is that injunctions are extremely difficult to obtain. This increase in popularity is largely due to some perceived and real advantages that the ITC offers over district courts, and the fact that the ITC has expanded its scope of influence. For example, the ITC has relaxed the domestic industry requirement and more recently the ITC has been expanding its more common limited exclusion order to cover even downstream products of other entities containing the infringing product. However, the Federal Circuit in the* Kyocero *case has clarified that the expansion of the more common limited exclusion order is an extraordinary measure that is available only under limited conditions, where it is difficult to identify the source of the infringing product and necessary to prevent a party attempting to circumvent an order limited to products of named persons.*

***How do you see the US patent environment developing over the next five years?***

***WER:*** *The US patent environment over the next five years will be very similar to that of the last five years, with some slight improvements in the patenting process. It will still take several years to obtain a patent; inventors will still be patenting business methods; and biotech firms will still be able to obtain substantial IP protection (even if human genes* per se *are found unpatentable).*

*On the litigation side, it appears likely to continue to be the extremely expensive endeavour it has been. However, there are some bright points, such as the recent passage of legislation to establish a 10-year pilot programme to enhance district court patent expertise in six courts. The bill will not create speciality patent courts, but will instead encourage judges who are experienced and interested in patent litigation to step forward and be assigned patent cases in those districts.*

***PC:*** *Five years is getting to be a very long time for predictions; just look at where the global economy was three years ago. Even looking two years into the future may be difficult because we have a presidential election coming up within that period. If there is a change in administration, the changes may propagate like ripples in a pond. For one thing, a change in administration could well result in a change to the director of the USPTO. A new director may decide to revive previous attempts to change applicant behaviour by enforcing numerical limits on application size and number, rather than by making the USPTO more flexible in responding to the needs of the community.*

***TJH:*** *As for the US patent environment over the next five years, other than the usual ebb and flow of court decisions and USPTO regulations, I think we are likely to see a resurgence in the need for cooperation between IP counsel and regulatory counsel as the FDA, the courts and the companies try to sort out the application of the biosimilars legislation, much like the early years after Hatch-Waxman. Also, in light of the biosimilars legislation and recent court rulings tightening disclosure requirements, we may see a subtle shift in filings as companies in the biologics area reconsider what to patent and when.* ■

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