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Electronic intellectual property

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Over the years I have dealt with many topics surrounding the use of spectroscopic data in electronic form – the use of data transfer standards being only a small part. However, what I have never touched on to date is how using and relying on electronic data can help or hinder the legal side of your daily business. Although there has been widespread acceptance and, in the case of the United States FDA 21 CFR part 11, specific guidelines on how electronic and paper records can be made equivalent, I was surprised to hear worries expressed recently about the acceptability of electronic records in patent cases. In fact, for a long time, electronic records have played significant roles in law suites and regulatory investigations.

European vs USA practices

Despite measures to bring more commonality between European and US patent law, a wide gap still exists especially when it comes to challenges to patents. The European approach is to recognise the "first to file" whereas the United States of America recognises the "first to invent". This essentially means to achieve "priority" in Europe you simply (!) need to win the race to submit a patent application and have it granted. In the USA this submission procedure can go to completion but here a major difference arises in that subsequently the patent can be challenged. The challenger then needs to bring evidence of prior invention that may not previously have been in the public domain.

USA patent interventions

The European system is simpler in that the priority rights to a particular invention are granted defining the date of the invention as the date of submission of the patent application. The USA system concentrates on the Inventor and the actual date of the invention. This can lead to a profitable business for the patent lawyers where a dispute over the actual date of the invention arises. Thus we have the basis for the so-called Patent Interventions in the USA.

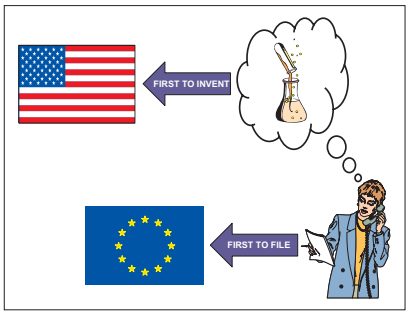

Figure 1. Patent priority is assigned in Europe on a "first to file" basis in contrast to the USA where a filed patent can be challenged on a "first to invent" basis.

During a patent intervention it is often the case that the defendants will be required to make all documents relating to a particular invention open. How does this apply to electronic records? Well, first, it is important to note that in the USA the Federal Rules of Evidence (FRE) govern the admission of evidence in federal courts and USPTO interferences.

In order to address the question of admissibility of electronic records the US Patent and Trademark Office issued an Official Gazette notice over seven years ago. The OG Notice 12 January 1998 specifically stated "…pursuant to 37 CFR 1.671 electronic records are admissible as evidence in interferences…". See http://www.uspto.gov/web/offices/com/sol/og/con/files/cons119.htm.

More recently, Part 41 section 41.152 of Subpart D "Contested Cases" and 41.154 "Form of Evidence" no longer even differentiate between electronic and other forms of evidence. Key is that the FRE apply to interferences "except as otherwise provided in this subpart" – and nowhere in the subpart is any rules to suggest that electronic evidence is inadmissible.

Many court cases in the USA and also in Europe are won or lost in preliminary hearings outside the actual court. If you cannot persuade a judge that you should be allowed to present your crucial laboratory notebook containing the spectrum that proves you were first to invent that new drug, then it obviously cannot weigh in your favour during the main proceedings.

So what must any evidence show in order to be admitted? Well in legal language, as long as the evidence has:

"A tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence"

it should be admissible in the USA provided the requirements of FRE Rule 803(6) are met.

Why are laboratory notebooks not rejected as hearsay?

If I were to try and give evidence in a murder trial that I had heard in the pub that John had heard from Peter that Jane had murdered Susan it would be inadmissible as hearsay.

So why do such restrictions not apply to laboratory notebooks or spectra measured by technical staff many steps removed from the actual court case under discussion?

To have any record admitted, the record must be admissible under a

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specific rule or rules. When an average staff retention period in the USA of seven years is regarded as something special, there is obviously often nobody with first-hand experience of events available to testify in court cases.

To avoid this dilemma an exception to the hearsay rule has been created for all business records – such as your spectra and the associated laboratory notebooks. Such records, whether electronic or paper, are admissible under the Business Record Exception (FRE Rule 803(6) Records of Regularly Conducted Activity). Records may be kept "in any form" but it must be possible to prove that

(a) the record was made at or near the time by a person with knowledge,
(b) that the record was kept in the course of regularly conducted business activity and
(c) it was the regular practice of the business activity to make the record. This can be shown by testimony or written declaration by the custodian or a qualified witness.

Now if you are fortunate enough to have your electronic record-keeping compliant under say FDA 21 CFR part 11 you should be able to put together the case that your records meet (a), (b) and (c) with very little problem.

Now for a patent interference or defence to be successful the records submitted must prove not only conception, but also reduction to practice, diligence and corroboration as proof of inventive acts whether electronic or paper. This might mean that your laboratory notebook included the idea for a new drug and its potential structure, the experimental attempts to synthesise the drug over a period of time, the analytical spectra from various techniques proving that the compound you synthesised was indeed that which you were trying to make.

Just because it's on paper doesn't mean it's admissible!

In an interesting ruling in the USA, Chen vs Bouchard Interference No. 103,675, the fact (a), (b) and (c) above were not found to be proven meant that paper laboratory notebooks were not allowed as evidence in this particular case as they did not meet the criteria to qualify under the Business Record Exception.

Chen was unable to prove that the paper notebook belonged to their scientist and were also unable to provide enough evidence of policies regarding the maintenance of the paper laboratory notebooks.

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Although this case does not explicitly deal with electronic systems it is clear that records must meet certain standards of admissibility whether paper or electronic and a failure to meet these standards of admissibility will have the same detrimental effect before a court regardless of the storage media.

Sarbanes–Oxley Act

Although you may never have heard of Sarbanes–Oxley it is worth pointing out that in 2002 a new law was enacted in the United States with far-reaching powers that, although targeted at the revelation of financial irregularities, covers "any matter within the jurisdiction of *any* department or agency of the US". This falls under the remit of the SEC (Securities and Exchange Commission) who many regard as even more aggressive than the FDA and has created criminal penalties around record handling. If you have any business dealing with the US you and your regulatory affairs people should be up-to-date on what is required here. See: http://www.sec.gov/spotlight/sarbanes-oxley.htm

Civil procedure law both at federal and state level requires information sharing in litigation and means that you have an obligation to retain records from the start of any case. They now explicitly include metadata! So if your company doesn't have an record retentions policy covering regular systematic review of all paper and electronic records for retention or destruction – it might be worthwhile thinking about getting one in place – and ensuring its enforcement!

Summary

Although there exists no specific case law on electronic laboratory notebooks, US courts have consistently found electronic records to be admissible. Electronic records are not inherently less reliable and qualify for submission under the business record exception if they are kept under the normal course of business criteria applicable to all records detailed above.

Generally, there is no dispute about the submission of electronic records – there is no presumption by courts and juries that electronic records are implicitly untrustworthy. Indeed the entire field of computer forensics and the associated high profile criminal prosecutions would not be possible if this was not the case.

Any risk perceived as being attached to getting an electronic record accepted by a US court is the same as having equivalent paper records ruled inadmissible. Where electronic records have been held correctly it can often be easier to prove the electronic records meet the submission criteria and substantially easier to prove conception, reduction to practice, diligence and corroboration as proof of inventive acts over time.

If you talk to analytical laboratory managers in industries where corporate patent lawyers often come hunting for the analytical data some time after it has been measured they will testify that it is significantly easier to meet record requests when the records are held in electronic form.

Indeed, as a final worrying kick in the tail, it is worth remembering that judges will now expect you to have all your electronic records in order and be capable of producing them on-demand in a timely fashion (as it is the right of anyone challenging your US patent to insist upon you producing – at your cost – ALL records with any relevance to a particular invention). If you cannot do this to their satisfaction they may well instruct a jury to find against you by default as has recently happened to the cost of a well-known electronics company. Such cases make the return-on-investment arguments to senior management somewhat simple!

Talkback

As this seems to be a fairly hot topic at the moment I would welcome further discussion that we can either keep confidential or reproduce here on these points if desired.

For a more detailed discussion of the issues the US law firm Foley and Lardner produced an informative publication way back in 1999 which is available under http://www.foley.com/publications/pub_detail.aspx?pubid=608