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COMMENTS ON 2014 PROCEDURE FOR SUBJECT MATTER ELIGIBILITY ANALYSIS OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PRINCIPLES, NATURAL PHENOMENA, AND/OR NATURAL PRODUCTS

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We submit that the following passage from page 2 of Professor Cole's comments filed at the USPTO on June 15, 2014 summarises the position of many commentators both at the forum and in subsequent written submissions:

> "It is submitted that the second paragraph of the Memorandum over-states the need for a new procedure concerning application of the law relating to natural products. The view as to what amounts to a significant difference from what exists in nature is unduly demanding, and it is not apparent that any meaningful change in the law and practice relating to chemicals derived from natural sources, proteins or peptides and other substances found in nature is required. For all these materials the correct legal test, as explained below continues to be the long-established test of novelty (including novelty of form, concentration or purity and new utility carried forward from many long-established decisions and approved in *Chakrabarty*). As regards nucleic acids, as discussed below, it is strongly arguable that as a minimum position isolation as a molecular species obtained *in vitro* rather than predicted *in silico* and definition by a molecular formula (nucleotide sequence listing) and credible new utility should suffice for patent-eligibility."

(a) Respect for the Supreme Court's decisions means accepting the results in the cases before them. It does not require extending the reasoning adopted to other very different fact situations.

Thus, in the *Myriad* case, the Court's holding was that isolated human DNA was not patent-eligible merely because it had been isolated – though cDNA was, because it was not a natural product. The alleged existence of free-standing 'judicial exceptions' to the express provisions of §101 contradicts the opinion of Justice Berger in *Chakrabarty*: that the court's task is the narrow one of determining what Congress meant by the words it used in the statute; once that is done, its powers are exhausted. The theory that the patent statute is not a complete code and must be supplemented by 'judicial exceptions' – for example, that 'laws of Nature' are not patentable[1] - raises complex issues of the respective powers of the Court and Congress. Prudence suggests that holdings of the courts on §101 should so far as possible be interpreted as explanation of the language of the statute rather than as judicial legislation limiting the statute. For example, the findings in *Chakrabarty* and *Myriad* invoking *Hartranft* and other tariff cases are best understood as clarification of the statutory term "manufacture". Modern codifications of the law are complete. They may require interpretation – but they do not require addition. Additions are the province of the legislature, not the judiciary.

The question accepted for decision by the Supreme Court in *Myriad* was "Are human genes patentable?" The answer (which is what is now the law) was "Not as a result of mere isolation – though cDNA is". The general question of 'judicial exceptions' or 'products of Nature' was not before the Court. Had the broad question of patenting 'products of Nature' been before the Court, the argument would have ranged much more broadly, and many more parties would have intervened to make points. What the Court would have decided on the broader question is no more than speculation. There is no reason to change practice – particularly in such a dramatic fashion. If the broader question needs to be decided, it can if necessary (when a suitable case arises) go back to the Supreme Court. Meanwhile, all that

[1] To CIPA's knowledge, no country in the world grants patents for 'laws of Nature'. But they do this without special 'judicial exceptions' but rather by relying on conventional and universal rules about novelty and obviousness. This 19th century dictum about 'laws of Nature' finds no useful application in modern patent laws.

the USPTO need (and should) do, is to refrain from issuing patents on 'isolated DNA' unaccompanied by significant new utility.

(b) The proposed new rules would put back by decades the US government's efforts to obtain pro-innovation common standards in patent laws worldwide.

For many years now, successive US Governments have laboured to encourage the world-wide adoption of strong and uniform levels of protection for intellectual property – particularly patents. An important object has been to prevent other countries appropriating US inventions without permission or recompense. A major success of US Government policy has been the negotiation of the TRIPs Agreement. This sets minimum levels of intellectual property protection required for membership of the World Trade Organisation. That agreement has been a powerful incentive to many countries to improve their IP laws. TRIPs has been a cornerstone of the USA's efforts to strengthen intellectual property laws worldwide.

These efforts have been applauded and enthusiastically supported by most developed countries: both developed and developing countries have changed their laws to conform to TRIPs. The Supreme Court decisions discussed above, correctly interpreted, are fully compatible with TRIPs. But it is by no means clear that the new USPTO guidance is.

For many years now successive US governments have been making efforts to encourage the rest of the world to adopt uniform and sensible rules on intellectual property – and in particular patents. These have slowly borne fruit – for example, in increased membership and use of the Patent Cooperation Treaty, in adoption of the Patent Formalities Treaty, and above all in the extension of WTO rules to intellectual property, in the Trade-Related Intellectual Property rules (TRIPs). The USA has been willing to change its own law to reflect more closely what the rest of the world does. At present, US negotiators are hoping that other countries will in their turn sacrifice tradition for uniformity in law, by adopting the US practice of 'grace periods'. A broad (and completely unnecessary) interpretation of the Supreme Court decisions, such as is proposed in the new rules, will be a severe setback to such efforts. If the USA does an about-turn in such an important policy area, other countries will be concerned. The *Chakrabarty* decision influenced many developed countries. This abrupt change in practice in USA will not necessarily be followed in other countries – immediately, or at all. So, divergences between the laws of different countries increase. Why change to the USA's way of doing things when the USA has just changed its own practice so radically – and may do so again?

(c) What will be the effect of construing the Supreme Court's decisions broadly?

The effect will be that many investments made in biotech research will become unfruitful. This will be a profound discouragement to further investment in an area that offers wonderful opportunities for relieving human ills all around the world. One specific (and important) problem is that of antibiotics. Pathogens developing resistance to antibiotics are a major problem worldwide. New effective antibiotics are urgently required (see, for example, the proposed GAIN Act -H.R.2182, Generating Antibiotic Incentives Now Act, introduced into the House in 2011). Nearly all effective known antibiotics are 'natural products'. It is likely that new ones will be, too. How can private firms be expected to search for – let alone develop – new antibiotics if they are uncertain if they will be able to obtain effective patent protection?

One major defect of the Court's decisions is lack of clarity and consistency – in itself a powerful disincentive to speculative investment. The USPTO's new proposals (even if they were otherwise acceptable) would do nothing to reduce this unclarity.

The Guidance

We have the following comments on the Guidance and its Examples:

At page 2 the Office explains that there has been a long-standing rule against patents on naturally occurring things. CIPA disputes the existence of that rule in the breadth set out in the guidance, and argues that it runs counter to what was previously regarded as settled US domestic law. That objection goes to the root of the guidance, which should be reconsidered in its entirety.

Example A refers to a stable energy-generating plasmid which provides a hydrocarbon degradative pathway and which is considered to be ineligible because there is no structural difference between the claimed plasmid and naturally occurring plasmids. If that example is retained without change, Examiners will be instructed that all sequences identical to naturally-occurring sequences are ineligible. Under the criteria in the European Biotechnology Directive (one objective of which was to bring EU laws more closely into line with those of USA) it would plainly be patent-eligible.

The plasmid pAC1 referred to in the submissions of Professor Cole at pages 17-19 we suggest provides an even more representative and instructive example. The following distinctions between that plasmid and the BRCA1 sequence considered in *Myriad* would in our submission be helpful to examiners:

> "In contrast to the BRCA1 sequence considered in *Myriad* the plasmid was isolated *in vitro* and not simply reconstructed *in silico* and is capable of chemical manipulation using restriction enzymes. Its novelty and utility falls to be judged by a biochemist from the standpoint of practical manipulation to produce hybrid vectors and not simply by a geneticist from the standpoint of its informational content.
>
> The plasmid has the new name pAC1. It has new characteristics because in pure form it can be manipulated at defined sites by restriction enzymes, whereas that is not possible with the plasmid as it occurs in nature. It has new utility because it can be used in genetic engineering to form hybrid vectors that can be reintroduced into *Acremonium* species to promote antibiotic synthesis. It therefore satisfies the *Hartranft* test approved in *Chakrabarty* and subsequently approved in *Myriad*. The use to which the plasmid can be put is a new use and not the mere consequence of its possession (see the dissent of Judge Bryson in *Myriad*, subsequently approved by Justice Thomas). Selection and isolation has therefore created a new product whose utility goes beyond simple isolation from the surrounding cellular material."

Example B holds that purified amazonic acid isolated from the Amazonian cherry tree and effective against cancer in manageable doses is not patent-eligible because it is not significantly different from the natural product. Arguments in support of the importance and public interest in such products remaining patentable are set out in the submissions of Thomas DesRosier of Cubist:

> "Over the coming years, the number of drug compositions derived from naturally occurring small molecules is likely to increase. The

development of combinatorial chemistry through the 1990s and 2000s led many pharmaceutical companies to move away from natural products, but that trend is reversing as synthetic small molecule pipelines are drying up. New tools are also emerging to allow scientists to access and study natural products. Scientists have estimated that less than 1% of all microorganisms that have been seen under a microscope have been cultivated. Improved culture procedures are making it possible to grow microorganisms that were previously unavailable, and to study the molecules that they produce. Advances in oceanography and environmental science also are making it possible to collect samples from previously inaccessible areas. Furthermore, recent findings suggest that organisms produce a host of novel products when grown together instead of separately providing new products for researchers to study. Molecular biologists have also discovered silent genes that code for products hidden in bacterial and fungal genomes and they are working to find ways to express and isolate these previously unknown drug candidates.

Researchers must now build upon these discoveries to develop new therapeutic compositions and methods of making and using them. Significant inventive efforts will be required to realize the potential of such naturally-occurring molecules for providing new pharmaceutical treatments. These advances have the potential to produce important new drugs, but only if the economy and the patent system provide appropriate incentives for natural products-related research. Cubist, for example, has invested over $1 billion to bring important life-saving antibiotics to the market, including CUBICIN® and DIFICID®. Unlike diagnostic methods, which were at issue in several of the recent patentable subject matter cases, antibiotics require extensive clinical trials, with substantially more time and resources invested to bring a product to market. If the USPTO now goes beyond the Supreme Court's requirements in refusing to grant patents on inventions derived from or relating to natural products, Cubist and other companies like it will not be able to protect their research and development investments. Therefore, the Guidance should not extend recent Supreme Court decisions to unduly restrict patentable subject matter with respect to natural products-related inventions."

At the May 9 Forum, disapproval of this example was noted by Dr Hans Sauer on behalf of the Biotechnology Industry Association (BIO), Susannah Sundby (Chair, AIPLA Biotechnology Committee), Kenneth Sonnenfeld and Courtnay Brinkerhoff. Dr Brinkerhoff quoted Sherry Knowles *et al*. and noted that 50% of all small molecule drugs are natural products and that 75% of antibacterial drugs are natural products or are derived from natural products. Disapproval of this example and the reasoning on which it is based has been expressed in written comments by the Japan Intellectual Property Association, the Japan Patent Attorneys Association, the Japan Pharmaceutical Manufacturers Association, Institut Pasteur, Cubist, John Beutler (US National Cancer Institute), Professor Cole, Leslie Fischer (Novartis), Joe Liebeschuetz and Robert Lyons. Arbitrary exclusion of newly isolated chemical entities with valuable properties places USPTO practice is a novel and highly unwelcome feature of the guidance. CIPA agrees with this body of opinion and submits that the example should be re-written to support patent-eligibility or withdrawn.

Example C refers to a fountain-style firework and asserts that gunpowder is patent-ineligible being a mere mixture of naturally-occurring ingredients. Although outside the scope of our detailed comments, it is noted that this theme has been developed in training slides for examiners. That proposition runs counter to the opinion of Curran J. in *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280 (DC 1957) where the following definition of a "composition of matter" appears:

> "This phrase covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."

That definition was approved by the Supreme Court in *Diamond v Chakrabarty* with the additional comment that:

> "In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope."

The eligibility of mixtures of this kind is asserted in the comments of Dilworth IP Law and of Professor Cole. CIPA agrees with these comments and is aware of no reason why a mixture of materials, even if naturally occurring, should fall outside the plain language of §101, especially where as in the case of gunpowder the ingredients are altered (in the case of gunpowder by the physical process of fine division) and mixed by the hand of man and give rise to new utility. The idea that a mixture of materials such as this – if novel – would be patent-ineligible is difficult to take seriously. It is a good example of Professor Cole's thesis – a new utility – here, literally explosive - should confer patentability.

Example D is based on the fact pattern in *Funk Brothers v Kalo* and holds the following claim to be patent-ineligible because as a whole it does not recite something significantly different from the natural products:

> "An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific."

It is not apparent how a mixture of different strains of bacteria can fall outside a "composition of matter" as approved in *Shell Development* and *Chakrabarty*. If the mixture falls within the statutory language it is not apparent how mere recitation of its properties can by operation of law remove it from the scope of that language.

In his opinion Justice Douglas acknowledged the holding of the Circuit Court of Appeals that the inventor had made a new and different composition of matter. There is no suggestion anywhere in his opinion that this holding should be reversed. Instead Justice Douglas went on to acknowledge that the aggregation of select strains of the several species into one product was an application of the newly discovered natural principle, implicitly approving that holding.

What in fact was his holding is encapsulated in the following language at the end of his opinion, reflecting issues nowadays proper to §103 and not to §101:

> "Since we conclude that the product claims do not disclose an *invention or discovery* within the meaning of the patent statutes, we do not consider whether the other statutory requirements contained in 35 U.S.C. § 31, R.S. § 4886, are satisfied."

Justice Douglas cites the statutes, and makes no reference to any alleged 'judicial exceptions'. His holding that the aggregation of species fell short of *invention or discovery* within the meaning of the patent statutes made reference to his earlier *Cuno* opinion which, as is well known, concerned inventiveness and not eligibility. The argument in the quoted passage is that the newly discovered natural principle is irrelevant

to invention or discovery because it is not itself an eligible feature, and with that feature disregarded the claimed subject matter was hardly more than an advance in the packaging of the inoculants without relevant change in utility and did not meet the “flash of genius” standard of *Cuno* (now overruled by statute).

CIPA says that the quoted passage quoted on page 11 of the guidance should be understood in the context of those words within the statute in relation to which it was used and no others: i.e. what qualified as “invention or discovery” and not what qualified as a “composition of matter”. It should not be taken out of context or used to create rules never envisaged or intended by Justice Douglas. It is instructive to compare the holding of Justice Douglas with that of Justice McReynolds in *American Fruit Growers v Brogdex* 283 U.S. 1 (1931). In that case the claimed invention was fresh fruit rendered resistant to blue mould decay by the application of a solution of borax. The opinion discusses at some length the meaning of the word *manufacture* and the holding was that an orange, the rind of which has become impregnated with borax through immersion in a solution, and thereby rendered resistant to blue mould decay, is not a "manufacture" or manufactured article within the meaning of the patent law. It is apparent that pre-1952 the Justices were fully aware of the difference between eligibility issues (now the province of §101) and unobviousness (now the province of §103) and in their opinions used appropriate statutory language to identify the nature of the question addressed. Cubit argue that the opinion in *Funk Brothers* should be interpreted narrowly. The Japan Patent Attorneys Association argues that it was not really a case about natural product eligibility and CIPA agrees with that view for the reasons explained above. Views that the holding in *Funk* should be narrowly interpreted are expressed in the comments of Professor Cole, Liebeschuetz and Raczkovski. Those comments are supported by CIPA. The *Kalo* claim was directed to a patent-eligible composition of matter: whether it should survive the tests of §103 or §112 are separate issues.

CONCLUSION

For all the foregoing reasons, we urge the USPTO to withdraw all the proposed new Rules, and substitute them by the practice announced shortly after the Supreme Court's decision in *Myriad* – namely, to continue with prior practice, except for ceasing to grant patents on DNA identical in sequence with known natural DNA sequences and without novel utility.

30 July 2014