I am a U.S., European and British Patent Attorney. I am also an adjunct professor at Fordham University School of Law where I have taught a course on U.S. patent law for the last twenty years. I also taught courses on International and Comparative Patent Law at Fordham and at John Marshall School of Law in Chicago for many years. The comments made herein are my personal views and do not represent the views of the firm to which I am of counsel, any of its clients or any law school with which I am or have been associated.

It seems to me that part of the present problem on U.S. law on patent eligibility is that we are trying to use the concept of patent eligibility to cover three different issues:

1. What types of invention should be patentable?

2. What constitutes "invention"?

3. How to deal with what in my early days in England I would have called "free beer claims". (I claim free beer but I am not going to tell you how to make it.)

What types of invention should be patentable

Current U.S. law addresses this issue in two ways: by the statutory limitation to process, machine, manufacture, or composition of matter and if the invention falls within one of these categories the three "judicial exceptions": "Laws of nature, natural phenomena, and abstract ideas". Application of the first requirement has led to the exclusion from protection of types of invention that are patentable elsewhere, such as signals. It is, however, the second group that has caused the most problems because the courts have extended the concepts beyond the natural meanings of the words to exclude from patentability various things that are far from abstract, such as economic practices (including hedging, insurance, mitigating risk); commercial or legal interactions (including agreements in the form of contracts; legal obligations; advertising, and marketing or sales activities). Similarly, the exclusion for "laws of nature" has been held to exclude the completely non-natural method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder by administering a drug to a patient; determining the resulting metabolite levels in the patient's blood and using this information to determine whether the dose given is too high or too low by comparison with certain data on metabolite concentrations set out in the claim.

Decisions on whether inventions of these types should be eligible for patent protection are essentially policy issues. There has long been a general consensus that certain types of invention should not be patentable however meritorious they may be. Just over 50 years ago Dick Fosbury won the high jump in the Mexico Olympics by for the first time using a style of jumping (the Fosbury Flop) that enabled him to pass his entire body over the bar without his center of gravity ever having passed over the bar. Clearly a technological innovation, but not thought to be patentable for policy reasons.

Such policy issues should ideally be decided by the legislature. However, the results of attempts to do this in other jurisdictions such as the European Patent Convention and Japanese Patent law raise questions as to whether this is practicable. The laws in both of these contain laundry lists of prohibitions on for example patenting of therapeutic methods and computer programs "as such". The result has been that to meet the needs of industry the courts or other tribunals have had to "interpret" items on the list sometimes resulting in allowing or upholding claims that seem to be prohibited by the language of the legislation. For example, as first construed, such prohibitions apparently barred the patenting of new uses of old drugs. As the advantages of repurposing old drugs (they were already known to be safe and their side effects were known) became apparent, the practice in Europe and Japan, subsequently endorsed by the courts there, allowed claims either for methods of using known drugs for making medicaments for treating new disease (Europe) or medicines comprising an old drug for treating a new disease (Japan). Similar problems have arisen with computer-related inventions. This is not an ideal way to proceed. Technology is changing too fast and legislatures act too slowly to keep up with determinations of those types of inventions whose development and commercialization would benefit from patent protection. There are, however, some issues on which the legislature might be able to make a determination of whether a particular type of invention should or should not be eligible for patent protection such as business methods and sporting techniques. Once this is done, however, the question of how to establish policy for other types of invention becomes more difficult. But, if it is determined that other types of invention should be excluded from patentability, it is desirable that this be done in a broader context than deciding a dispute between two parties so that a wider range of views can be considered, for example, by use of public rule making within the frame-work of enabling legislation requiring some technical content consistent with Article 27 of the TRIPS Agreement.

What constitutes an Invention?

Over-simplifying a little, present U.S. case law sees an invention as being a specific inventive solution to a problem that can lead to a practical application. In doing this there has been a focus on the nature of the solution (it should not be well-understood, routine or conventional). The need for specificity being emphasized for example in a panel decision in **American Axle v Neapco** where a claim directed to a method for manufacturing a shaft assembly of a driveline system, which required tuning a mass and a stiffness of at least one liner without stating how to carry out the required tuning, was held not eligible for patent protection since it in effect said "use Hooke's law to work out what to do", i.e., use a natural law to do the job. In **American Axle,** five separate opinions by different combinations of judges were issued arguing for and against an *en banc* rehearing. Much of their content argued as to the true meaning of the Supreme Court's 1853 decision in **O'Reilly v. Morse**. Those agreeing with the panel decision saw the claim of American Axle's patent as analogous to claim 8 of Morse's patent which had been found to be invalid. That claim claimed the use of the motive power of the electric or galvanic current for marking or printing intelligible characters, signs, or letters at any distances and differed from the other claims of Morse's patent in that it made no reference to the particular ways of doing this described in his specification, whereas other claims in the Morse patent that

had been found valid had referred to use of specific means described in the specification. Those supporting the request for an *en banc* rehearing saw the panel decision as creating a new "nothing more" test to add to the complexities of deciding on patent eligibility and noted that in **O'Reilly v. Morse**, the Supreme Court had not drawn the distinction between Morse's claim 8 and his other claims that had been drawn by those concurring in denial of an *en banc* rehearing.

The issue of when an insight is developed to the point at which it becomes invention and whether there is invention in identifying a problem that is relatively easy to solve once it has been correctly identified (for example how to treat stomach ulcers once it had been determined that they were caused by *H. pylori* bacteria rather than smoking or diet as had previously been thought to be the case) is not unique to the United States. The last time that I am aware of when an attempt was made to do this on an almost blank sheet of paper was when the initial examination guidelines were written for the European Patent Office. These gave three examples of how inventions might be made:

1) The formulation of an idea or of a problem to be solved (the solution being obvious once the problem is clearly stated);

2) The devising of a solution to a known problem; and

3) The arrival at an insight into the cause of an observed phenomenon (the practical use of this phenomenon then being obvious).

The first of these was omitted when the Guidelines were substantially revised in 2012 as a result of no case decided by the Boards of Appeal of the EPO ever having been found to be a convincing fit to the test

It is the third of these situations envisaged by the original EPO Guidelines that poses the issues that the Federal Circuit grappled with in **American Axle** and **Illumina**. By applying the same test for patent eligibility that is used for innovations relating to abstract ideas to innovations based on newly discovered natural laws of phenomena, the Alice/Mayo test on its face denies patent eligibility to innovations that would meet one of the EPO's criteria for "invention". However, Judge Lourie's approach in **Illumina** seems consistent with this. Here he seems to have seen the claims as being directed to a specific practical application of a discovery of a natural phenomenon and a majority of his colleagues let that stand without voting for an *en banc* rehearing to determine whether he was right or not. On the other hand, in **American Axle** there was no specificity in how to apply the idea of tuning a drive shaft lining.

The need for specificity in what is claimed when dealing with this type of invention seems reasonable to avoid preclusion of others from being able to utilize the insight or discovery in question. On the other hand, it may be time to reconsider whether the discoverer or person having the insight should be deprived of all patent protection just because once the discovery or

insight occurs it is obvious how to apply it. It seems, however, that any such change would require legislation.

Relation between 35 USC 101 and 35 USC 112

The final issue is the current apparent overlap between the enablement requirement of 35 USC 112 and 35 USC 101 that was set out front and center in Judge Moore's dissent in **American Axle** and reflected in Judge Chen's comment

> The lesson to patent drafters should now be clear: while not all functional claiming is the same, simply reciting a functional result at the point of novelty poses serious risks under section 101.

While lack of specificity in claiming is clearly an issue in determining patent eligibility, the question of whether the specification provides an enabling disclosure of how to make and use the invention seems less clearly related to the question of whether the invention is eligible for patent protection. The way in which courts decide cases is of course dependent on how the parties have litigated it, but it would make the law easier to apply if it were clearer that there is only one test to apply to determine whether the specification discloses sufficient information about the invention and how to perform it. This should be the test of 35 USC 112. How to accomplish this is less clear.