



# THE SEDONA CONFERENCE

## *Framework for Analysis on The Role of Patents in Biopharma v. High- Tech Industries: Can One Patent System Effectively Accommodate Both? Project Charter*

A Project of The Sedona Conference  
Working Group on Patent Litigation  
Best Practices (WG10)

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## *Principles “At a Glance”*

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## *I. Introduction*

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The high-tech and biopharma industries are two poles of the patent ecosystem. The arguments for and against the value of patent protection in each industry often diverge significantly. Some biopharma industry participants point to the need for patent protection to counterbalance costs associated with long product development lead time, a high and unpredictable failure rate, low barriers to entry when a product comes to market, and the need to facilitate competitive market entry after an appropriate period of exclusivity. Others cite increased cost and diminished access to lifesaving medicines as countervailing considerations.

In contrast, in the high-tech industry, critics of excessive patent protection note that high-tech industries operate in a world of much faster product development, significant non-patent barriers to entry, multi-feature products potentially covered by thousands of patents, and much greater risk than any given patent will be overvalued due to holdup effects. On the other side of the debate, other market participants identify a need to reward innovative approaches as well as incentives to share innovation with the public rather than maintain advances as trade secrets to justify strong patent protection. These disparate economic realities lead to very different views of what is good, and bad, in patent law. And in the context of standards-essential patents, the arguments on both sides take on additional complexity.

Recently, the two industries' competing conceptions of the patent system have come to a head in the context of ongoing debate about the role of Section 101 in evaluating patent-eligibility. Many in the life sciences industry argue that the notion that pioneering advances in diagnostics and therapeutics should be ineligible for patent protection is both arbitrary and profoundly harmful to these industries. In the technology space, an equally vocal contingent points to the need to preserve Section 101 as a bulwark against vague, abstract, ambiguous patents that purport to cover mathematical algorithms and similar fundamental scientific tools used on a daily basis by software engineers and data scientists.

It has been a tenet of the patent system for as long as it has existed that one size does fit all: the same legal rules should apply regardless of technological field. And the only major industry-specific change to U.S. patent law—the Hatch-Waxman Act—has frequently been criticized as the cause of distortions that promote needless litigation and gaming of the system. But with major industries facing fundamentally different challenges and realities in product development and commercialization, is it time to reconsider whether one patent system can fully serve the needs of today's complex global economy? The goal of this Sedona commentary drafting team is to examine the practical reasons pushing the two industries toward different objectives, and to consider to what extent a single legal regime can work for both.

*This Commentary does not address*

Key issue: What considerations should apply in trying to determine whether patent law should apply agnostically to all technology areas versus whether the law should make accommodations in the case of specific technologies?

[Proposed] Principle No. 1

**[Proposed] Principle No. 1 – In all technology areas, the scope of patent protection should strike a balance between adequately rewarding inventors on the one hand while protecting the right of the public to innovate on the other hand.**

**A. ISSUE NO. 1: IDENTICAL RULES VS. IDENTICAL POLICIES**

Key Issue: Does striking a consistent balance across technology areas necessarily mean adopting identical rules across technology areas?

[Proposed] Guideline No. 1

[Proposed] Guideline No. 2

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**B. ISSUE NO. 2: *SUI GENERIS* PROTECTION**

Key Issue: Should policymakers look toward *sui generis* forms of protection (like FDA exclusivity) to address policy concerns that cannot adequately be addressed through patent laws?

[Proposed] Guideline No. 3

Etc.

## ***II. Patent-Eligible Subject Matter***

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- Key issue: Does Section 101, together with Supreme Court case law to date, strike the same balance between rewarding inventors and protecting the public in the biopharma space as in the technology space?

**[Proposed] Principle No. 2 – Case law can and should acknowledge that the overarching goal of striking a consistent balance between the interests of inventors and the public may result in rules on patent-eligibility that differ between industries.**

### **A. ISSUE NO. 1: LAWS OF NATURE VS. DIAGNOSTICS AND THERAPEUTICS**

Key Issue: Is it consistent to say that laws of nature should not be patent eligible while also maintaining that diagnostics and therapeutics may be patent-eligible?

[Proposed] Guideline No. X

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### **B. ISSUE NO. 2: MATHEMATICAL ALGORITHMS VS. BIOINFORMATICS**

Key Issue: Is it consistent to say that mathematical algorithms should not be patent eligible while also maintaining that bioinformatics may be patent-eligible?

[Proposed] Guideline No. X

### ***III. Functional Claiming***

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- Key issue: Do the policy considerations underlying the prohibition against functional claiming apply with equal force in the technology and biopharma spaces?

**[Proposed] Principle No. 3 – Case law should consider the underlying policy rationale against functional claiming when applying the rules in technology areas far afield from those in which the rules were developed.**

#### **A. ISSUE NO. 1: CLAIMING ALL WAYS OF TRANSMITTING DATA OVER A WIRE (*MORSE*) VS. CLAIMING ANTIBODIES**

Key Issue: Is there a principled difference between functional claiming for antibodies and the type of claim that the Supreme Court found beyond the scope of patent protection in *Morse*?

#### **B. ISSUE NO. 2: FUNCTIONAL GENUS CLAIMS**

Key Issue: Is the prohibition against functional genus claims in the biopharma field tied in a principled way to the policies underlying the prohibition against functional claiming?