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Vanda Swings for the Fences and Asks the Supreme Court to Heighten the Standard for Obviousness

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April 9, 2024, 8:06 AM
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Among the most established standards in patent law is that obviousness requires a motivation to combine the prior art with "a reasonable expectation of success." The Federal Circuit alone has employed the "reasonable expectation" formulation in hundreds of opinions spanning the past four decades. In a recent petition to the Supreme Court, Vanda Pharmaceuticals, which is becoming one of the most aggressive litigators in the pharmaceutical industry, is now arguing that this standard is contrary to the Court's precedent, particularly the seminal obviousness holding in *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). Instead, Vanda argues that the Court should adopt a more exacting "predictable results" standard. This change to the obviousness standard would alter the balance between patent holders and patent challengers and significantly impact the pharma and biologics industries.

Vanda's petition for cert arose in the context of a Hatch-Waxman action against Teva and Apotex where two of Vanda's patents covering its tasimelteon drug for treating rare sleep disorders were held invalid for obviousness. In affirming the district court's invalidity ruling, the Federal Circuit emphasized that "[o]bviousness does not require certainty – it requires a reasonable expectation of success." After the Federal Circuit denied Vanda's request for rehearing, Vanda filed its petition for cert.

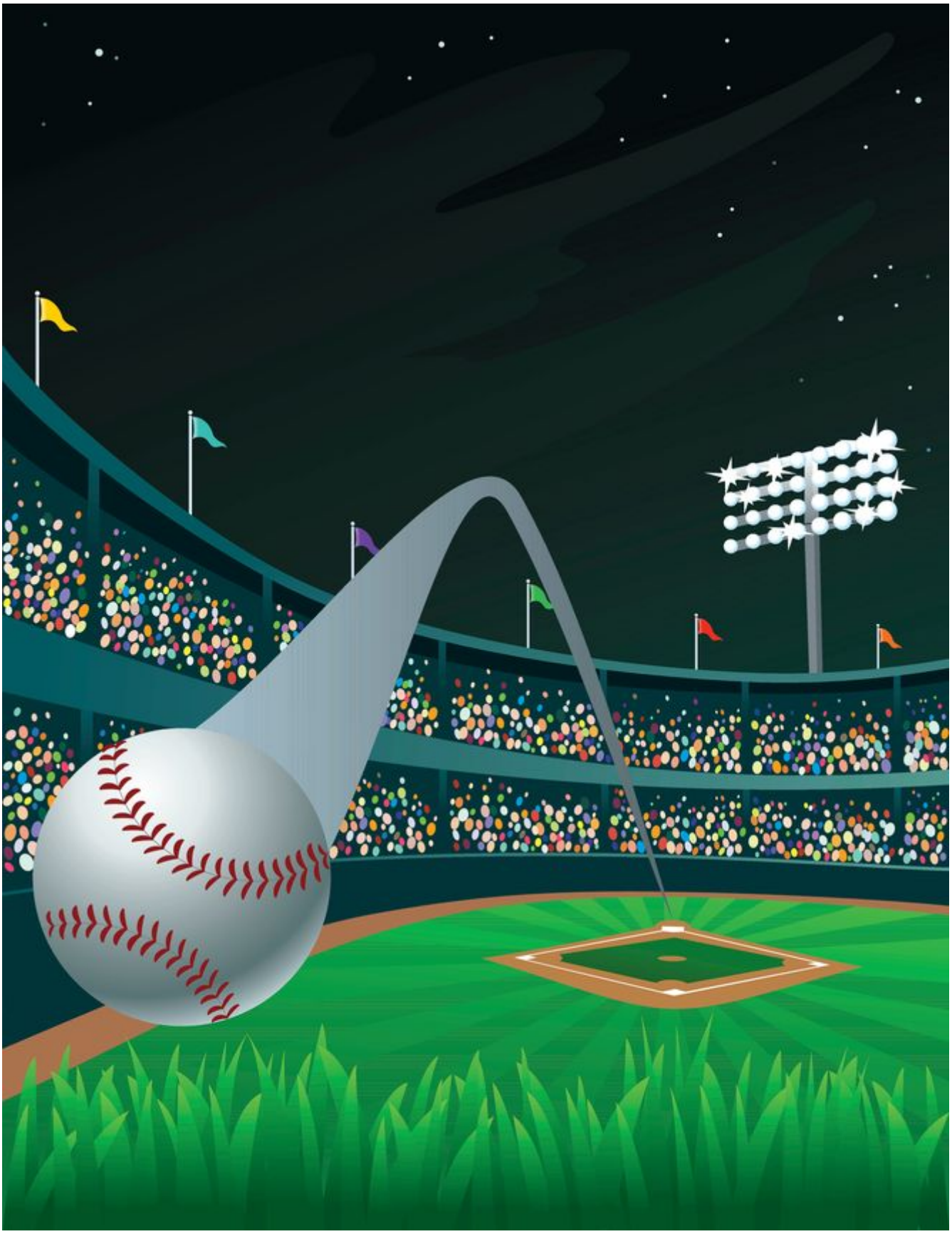
The crux of Vanda's argument is that the "reasonable expectation" standard is a creature of the Federal Circuit that the Supreme Court has never endorsed, and arguably put to bed in *KSR*

when it held that a "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Vanda argues that predictability is a higher standard because "a skilled artisan can reasonably *expect* success long before that success could be deemed 'predictable.'" According to Vanda, the expectation standard is particularly harmful in the chemical arts, where discovery typically follows from experiments: "The very fact of designing an experiment in a pharmaceutical may give a reasonable expectation that the experiment would succeed; it would, after all, make little sense to conduct an experiment if it were expected to fail."

Teva and Apotex initially waived their right to respond to Vanda's petition but filed an opposing brief after the Supreme Court requested a response. In addition to arguing that cert is inappropriate because Vanda did not raise this issue below, and because Vanda's patents would be obvious even under a predictability standard, the opposition disputes that Supreme Court precedent is at odds with the reasonable expectation standard: "In *KSR*, for example, the Court cited with approval its own prior conclusion that 'when a patent "simply arranges old elements with each performing the same function it had been known to perform," and yields no more than one would expect from such an arrangement, the combination is obvious.'"

Finally, Teva and Apotex counter Vanda's policy argument by pointing out that a predictability standard would "make it dramatically more difficult to invalidate patents as obvious than has ever before been the case," which in the pharmaceutical space "would reduce the availability of generic drugs, resulting in higher prices for payors and lower drug accessibility for patients."

Vanda's petition has been distributed for conference on April 19. If granted, the case will likely garner more attention than any patent case has for a long time.



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