

## קריטריונים לבחינת שאלת הצעד האמצאתי בארה"ב בשטחים טכנולוגיים בהם לא ניתן לצפות את תוצאות המחקר לאחר KSR

הוראות הבחינה החדשות עוררו דאגה שמא דחייתן של בקשות פטנט בשל העדר צעד אמצאתי תהיה כה קלה, עד שלא ניתן יהיה למעשה לקבל פטנט, פרט למקרים נדירים ביותר. עתה, בחלוף יותר משנה וחצי מאז KSR, הערכאות המשפטיות הרלוונטיות, כולל ערכאת הערעור של ה-USPTO (Board of Patent Appeals and Interference; BAPI) וה-CAFC מגלות חוסר נכונות לפרש את KSR כמאפשר, באופן גורף, הפעלת חוכמה שבדיעבד וויתור על מבחן ה-TSM. אומנם KSR הביא לכך שקשה יותר היום לקבל פטנט, אולם השינוי, לפחות ככל שהדבר אמור לגבי מדיניות הערכאות השיפוטיות, אינו גדול כפי שנחזה תחילה. בפרט, ה-CAFC ממשיך להפעיל את ה-TSM כמבחן עיקרי לבדיקת צעד אמצאתי בשטחים טכנולוגיים בהם התוצאות אינן ניתנות לחיזוי מראש, ואינו מפעיל את מבחן ה-obvious-to-try בשטחים אלה.

החלטה חשובה מאד של ה-CAFC, מהעת האחרונה, על פיה נראה שהקריטריונים לבחינת צעד אמצאתי שהיו קיימים לפני KSR ממשיכים להתקיים גם בעידן שלאחר KSR, לפחות ככל שהדבר אמור לשטחים בהם התוצאות לא ניתנות לחיזוי מראש כמו הכימיה ומדעי החיים, תידון להלן.

למרות העמדה המשפטית של ה-BAPI ושל ה-CAFC לפרש בזירות את KSR ככל שהדבר אמור בהפעלה של חכמה שבדיעבד בבחינת שאלת הצעד האמצאתי, בוחנים ב-USPTO מפעילים באופן שגרתי שיקולים, שבמהותם יש הפעלה של חכמה שבדיעבד, בהעלאת השגות של העדר התקדמות אמצאתית. הגם שטיעונים משפטיים על בסיס החלטות ה-CAFC יכולים לסייע בבחינת בקשות כדי להתגבר על השגות של העדר התקדמות אמצאתית, יהיה כנראה צורך גובר לערער על השגות של בוחנים בפני ה-BAPI, לפחות עד שהסטנדרטים הקפדניים יותר של הערכאות המשפטיות יחלחלו גם לבוחנים.

דיון נרחב יותר בעניין זה מופיע להלן.

### מחברים:

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ב-30 באפריל, 2007, בית המשפט העליון בארה"ב נתן את החלטתו בעניין KSR International Co. vs. Teleflex Ltd ("KSR"). מוקד ההחלטה היה הקריטריונים לקביעת התקדמות אמצאתית באמצאה KSR נחשבת ע"י רבים כאחת מההחלטות החשובות ביותר בענייני פטנטים שנתן בית המשפט העליון מזה שנים רבות עם השלכות מרחיקות לכת. אולם, פסקי דין שניתנו לאחר KSR מצביעים שהשלכות ההחלטה התקדימית הזו על שטחים כמו הכימיה והביוטכנולוגיה אינן גדולות כפי שניתן היה לסבור תחילה.

במשך כעשרים שנה לפני KSR, המבחן הקובע לעניין קיומו של צעד אמצאתי היה מבחן ה-TSM (Teaching, Suggestion, Motivation). מבחן זה נוצר על ידי ה-Court of Appeal for the Federal Circuit (CAFC). בית המשפט הגבוה ביותר לענייני קניין רוחני בארה"ב, ושימש גם את משרד הפטנטים בארה"ב (USPTO) בבחינת בקשות לפטנט. ב-KSR בית המשפט העליון בארה"ב קבע שמבחן זה אינו מבחן יחיד, וישנן דרכים נוספות לשלול קיומו של צעד אמצאתי.

יתרה מכך, בית המשפט העליון קבע שאין להשתמש במבחן ה-TSM בצורה נוקשה. בית המשפט ב-KSR נתן דוגמאות רבות למבחנים לבדיקת קיומו של צעד אמצאתי, אשר לפחות בחלקם מבוססים, למעשה, על הפעלה של חוכמה שבדיעבד. בין השאר קבע בית המשפט העליון, שבתנאים מסוימים, די בכך שהיה קיים מניע לבחון את האמצאה, בבחינת obvious-to-try, כדי לעקר אותה מצעד אמצאתי. לפני כן, הפסיקה הכירה בכך שרוב העיסוק המדעי הינו בחינה של אפשרויות שיש טעם מדעי לבחינתן, ולכן קבעה כי אין לפסול קיומו של צעד אמצאתי באמצאה רק משום שהאמצאה היא בבחינת obvious-to-try.

ענינו של הפטנט שנבחן ב-KSR הוא אמצאה מכאנית (שעניינה דושה ברכב). מכאניקה והנדסה נחשבים לשטחים טכנולוגיים בהם ניתן לצפות מראש את התוצאה במידה סבירה של וודאות. לעומת זאת, מדעי החיים וכימיה נחשבים לשטחים טכנולוגיים בהם התוצאות לא ניתנות לחיזוי מראש. לדוגמה, בד"כ לא ניתן לצפות מה יהיה האפקט הביולוגי של מולקולה או גורם ביולוגי מבלי לבחון את האפקט לאשורו. אשר על כן השאלה היתה, ובמידה מסוימת עדיין קיימת, באיזו מידה ראוי ליישם את המבחנים שקבע KSR על אמצאות בתחומים בהם התוצאות לא ניתנות לחיזוי מראש.

בעקבות KSR פרסם ה-USPTO הוראות חדשות לבחינת ענייני הצעד האמצאתי ("Examination guidelines for determining obviousness...")<sup>1</sup>. אחד השינויים הבולטים בהוראות החדשות גלום בדברים הבאים:

*The prior art reference (or references when combined) need not teach or suggest all the claim limitations; however, Office personnel must explain why the difference(s) would have been obvious to one of ordinary skill in the art."*

<sup>1</sup> Federal Register 72(195):57526-57535 (October 10, 2007)

## BACKGROUND

On April 30, 2007, the United States Supreme Court issued a decision in the case of *KSR International Co. vs. Teleflex Ltd* ("**KSR**"). The KSR decision focused on the criteria for inventive step to be applied in examining patentability. KSR is considered by many to be among the most important patent-related decisions in many years that may have far-reaching consequences.

The KSR decision criticized the rigid application of the **TSM** test ("Teaching, Suggestion, Motivation") for determining inventive step. Prior to KSR, the Court of Appeal for the Federal Circuit (CAFC), the highest legal authority for hearing intellectual property cases in the U.S. and the USPTO relied almost exclusively on the TSM test for determining obviousness.

In KSR the Supreme Court noted that "*A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post facto reasoning*". However, the Court gave ample examples of obvious analysis, which are proper in the eyes of the Court and which seem to be based on *post-facto* analysis and call for hindsight bias.

The KSR decision was accepted with mixed feelings by patent professionals: some felt that the Supreme Court did nothing more than call the CAFC to order in response to a bad decision handed down by the CAFC, while others were worried that under the new standards set by KSR, almost everything under the sun made by man will be considered obvious.

The patent at issue in KSR concerned a mechanical invention (directed to a vehicle control pedal). Mechanics and engineering belong to predictable arts, in which a prediction on the outcome can reasonably be made. In contrast life sciences, chemistry and medicine are non-predictable arts in which prediction is more difficult and less certain. For example, it is usually impossible to predict the nature of the biological effect of a molecule or biological agent without actual testing. Thus, the question was, and to some extent still remains, as to the implications of KSR on the non-predictable arts.

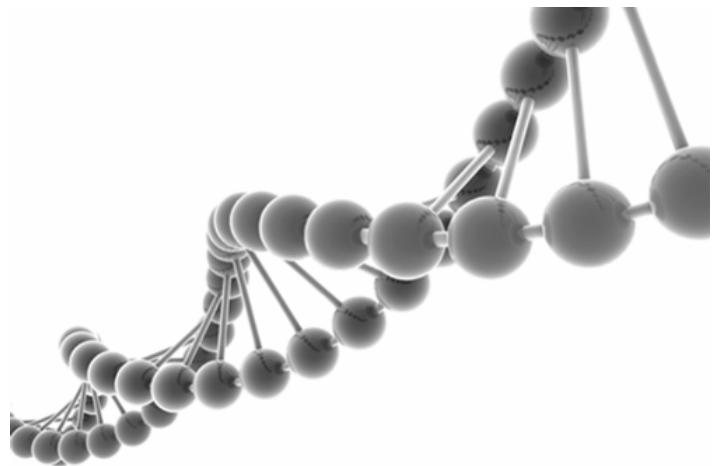
Following the KSR decision, the USPTO published new "Examination guidelines for determining obviousness..."<sup>2</sup> The main change reflected in the new guidelines is that:

*"The prior art reference (or references when combined) **need not teach or suggest all the claim limitations**; however, Office personnel must explain why the difference(s) would have been obvious to one of ordinary skill in the art."*

These guidelines, when initially published, were viewed as alarming. Now, more than 18 months after KSR, the relevant legal authorities including the Board of Patent Appeals and Interference (BPAI) and the CAFC are showing they are reluctant to interpret KSR as an unlimited license for hindsight. Although KSR seems to have made it more difficult to obtain a patent, the magnitude of the change in obviousness standards does not seem as great as originally feared.

In particular, the CAFC seems unwilling to abandon the TSM test, at least in the non-predictable arts. In several important decisions the CAFC has, indicated that a clear demonstration of motivation to make the invention is required to establish obviousness. In these unpredictable arts, an "obvious to try" rationale is deemed insufficient to establish obviousness because the results of such trial are unpredictable.

<sup>2</sup> Federal Register 72(195):57526 -57535 (October 10, 2007)



## POST-KSR PATENT EXAMINATION

Before KSR, when patent examiners rejected a claim for obviousness, they had to explain (1) how the combined references produced all of the claim limitations and (2) the motivation in the references themselves for a person of ordinary skill to combine the cited references. Sometimes, a reference was cited only for showing that such motivation existed at the time the invention was made.

Post KSR, the examiner's burden has been reduced. The cited references need not show all that is claimed and motivation does not necessarily have to be explicit in the references. This has caused a trend in USPTO Office Actions for using *post facto* analysis to show that obtained results were known to be desirable as a substitute for any explanation of suggestion or motivation to produce the invention.

The KSR decision explained that the TSM test was only one of the ways for establishing obviousness of an invention. In particular, KSR explained that an invention can be obvious in view of a publication in a non-related field; that "common sense" can be applied in obviousness analysis; and that "obvious to try" is a valid rationale for attacking the patentability of an invention. KSR also indicated that "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." This statement has made it easier for examiners to combine references.

The USPTO guidelines published in the Federal Register specifically indicate that "*The key to supporting any rejection [for obviousness] is the clear articulation of the reason(s) why the claimed invention would have been obvious.*" Despite this requirement, examiners often do not provide any explanation of the reason for which a skilled person would modify prior teachings to arrive at a claimed invention. Instead, examiners tend to rely upon teachings of the application being examined to establish obviousness. In many cases examiners simply declare results to be predictable, without making any effort to show that the results were indeed predictable at the time the invention was made. This appears not to be in line even with current USPTO examination guidelines that: "*[r]ejections on obviousness cannot be sustained by mere conclusory statement; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness*".

In practice, post-KSR patent examination freely applies hindsight and finds almost all inventions obvious. This seems to be true in the predictable arts (e.g. engineering) as well as in the non-predictable arts (e.g. chemistry and biology). As a result, success of patent applicants in overcoming an obviousness rejection is more limited and the need to appeal an examiner's objection to the BAPI more frequently arises.

## POST-KSR BPAI APPEALS

The Board of Patent Appeals and Interferences (BPAI) hears appeals against examiner's decisions. The BPAI decides about 150 cases each month. BPAI rulings in favor of applicants decreased by about 18% in the two months following the KSR decision. This decline in appeals success rate showed that KSR had an influence on standards of examination of inventive step, although possibly less dramatic than might have initially been expected.

In general, the BPAI seems to apply the new guidelines for examination more reasonably than Examiners. The BPAI still seems inclined to reward genuine innovation with a patent. Thus, although the Appeal procedure is costly and time consuming, it can be worthwhile, especially post KSR.

The attitude of the BPAI that genuine innovation is still worthy of a patent is consistent with decisions by the CAFC. The cases heard by the CAFC include appeals from BPAI decisions as well as appeals from district court rulings in patent litigation.



## POST-KSR CAFC DECISIONS

In a key post KSR decision of the CAFC – *Eisai Co. Ltd. et al v. Dr. Reddy's Laboratories et al*<sup>3</sup> ("Eisai") – the question of inventive step of a pharmaceutical invention was examined. The CAFC in Eisai made two important steps, which may remedy much of the bias towards hindsight called for by KSR at least in as far as the non-predictable arts of chemistry and biology are concerned.

The patent at issue in Eisai was US patent 5,045,552, which disclosed and claimed the compound rabeprazole, which is a proton pump inhibitor. Eisai sells the sodium salt of rabeprazole as Aciphex®, which is a drug used for duodenal ulcers, heartburn, and related disorders. Although the Court in Eisai discussed obviousness criteria in relation to a new chemical compound, the court's findings are relevant to the non-predictable arts in general.

The court in Eisai took advantage of the KSR court's permission to apply TSM analysis in a flexible manner.

The Eisai Court noted that KSR required that the prior art should provide some reasons for "narrowing the prior art universe to a 'finite number of identified, predictable solutions'". The Eisai Court summarized and stated that:

*"[t]o the extent an art is unpredictable, as the chemical arts often are, KSR's focus on these 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable".*

By interpreting the term "predictable solutions" to mean that the **result** of the solution is predictable, and not only the existence of the solution, the CAFC established a precedent that the KSR obvious-to-try analysis is often inappropriate in the unpredictable arts.

The Eisai Court explained that it applies the TSM test in a flexible way, as suggested by KSR, but still refers to "requisite motivation" despite the KSR ruling. Thus, the CAFC's Eisai decision suggest that when there is case law requiring demonstration of a motivation to establish obviousness, KSR does not cancel the requirement to demonstrate motivation.

The Eisai decision interprets KSR as merely broadening the sources from which motivation can be found. Thus, the CAFC brings back the requirement that a valid obviousness analysis should include a showing that a skilled person was motivated to make the invention at the time it was made.

<sup>3</sup> *Eisai Co. Ltd. and Eisai Inc. v. Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratory, Inc. and Teva Pharmaceuticals USA, Inc.*, Fed. Cir., July 21, 2008

<sup>4</sup> *In re Translogic Tech., Inc.* 504 F.3d 1249, 1257 (Fed. Cir. 2007)

The position of the CAFC that the TSM test, flexibly applied, is still an important tool for evaluating obviousness, was affirmed also in an earlier decision – *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc.* [CAFC March 31, 2008]. The case concerned topiramate, an anticonvulsive drug which resulted from initial efforts to develop a drug for treatment of diabetes.

In finding against obviousness, the CAFC re-affirmed that "a flexible TSM test remains the primary guarantor against a non statutory hindsight analysis such as occurred in this case". The court cited their own earlier decision<sup>4</sup> in which they indicated:

*"As the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of the invention."*

## SUMMARY

KSR has made it more difficult to obtain and defend a patent. USPTO examiners routinely present obviousness rejections that follow the format suggested by the post KSR examination guidelines. However these rejections are often "mere conclusory statements" as opposed to a recitation of "factual findings". Therefore, the rejections lack "articulated reasoning with rational underpinnings" as dictated by those guidelines.

This means that the applicant is often forced to go to the BPAI in order to get the application examined in accord with the post KSR examination guidelines. The BAPI usually offers today a friendlier forum for hearing reasoned arguments of non-obviousness based on a flexibly applied TSM test, particularly in the non-predictable arts.

The CAFC seems even more "patentee" friendly when addressing issues of obviousness than the USPTO. Hopefully, the Court's attitude will eventually be reflected in Office Actions issued by examiners during examination

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