THE REPUBLIC OF UGANDA

IN THE HIGH COURT OF UGANDA AT KAMPALA

CIVIL DIVISION

MISCELLANEOUS APPLICATION NO 209 OF 2021

1. **ADVOCATES FOR PEOPLE (AFP)**
2. **MUSA MUHAMMAD KIGONGO ::::::::::::::::::::::::::::::APPLICANTS**

VERSUS

1. **NATIONAL DRUG AUTHORITY**
2. **JENA HERBALS UGANDA LTD :::::::::::::::::::::::::::: RESPONDENTS**

BEFORE: HON. JUSTICE SSEKAANA MUSA

RULING

The Applicants filed this application for judicial review under Section 20 (5) and (7) of the Industrial Property Act 2014, Section 33 and Section 36 of the Judicature Act, Rule 3 (1) and (2), Rule 6(2) and Rule 8 of the Judicature (Judicial Review) Rules 2009 for;

1. A writ of Certiorari quashing the decision of the 1st respondent granting the 2nd respondent, Jena Herbals Uganda Ltd, permission to produce, sell and distribute Covidex drug, communicated to the public in a press release dated the 29th day of June 2021.

2. An order of prohibition restraining the 2nd respondent from production, sell and distribution of Covidex.

3. A declaration that the decision of the 1st respondent contained in the said press statement was irrational, legally improper, unjustified and reached without due regard to the law and rules of natural justice.

4. A declaration that Covidex drug belongs to Mbarara University of Science and Technology and not Jena Herbals Uganda Ltd.

5. Costs of the suit be awarded to the Applicants.

The grounds in support of the this application were stated briefly in the Notice of Motion and in the affidavits in support of the application by Kasibante Moses for the 1st applicant and Musa Muhammad Kigongo the 2nd applicant but generally and briefly state that;

1. That the decision and procedure followed by the 1st respondent to approve covidex as a supportive drug in management of viral infections including Covid 19 among others. and authorizing the 2nd respondent, Jena Herbals Uganda Ltd, to produce, sell and distribute the said drug whereas it is not the rightful owner or holder of the patent is not only illegal, procedurally improper, irrational, unconscionable, malafide and unjustifiable, but also prejudicial to public interests and the tax payers.

2. That on 14th day of 2021 Mbarara University of Science and Technology released a press statement signed by the Vice Chancellor in which he clearly stated that Mbarara University is the intellectual property holder of Covidex.

3. That on 14th day of June 2021, on the 1st Respondent's website, it released a press statement notifying the public that it had not authorized the production, sell and distribution of Covidex, and that no application to have the drug authorized had been received by it from the 2nd respondent.

4. That on the 29th day of June 2021, on NBS Television Mr. David Nahamya the Executive Director of the 1st respondent released a press statement which was also posted in the 1st respondent's website notifying the public that the 1st respondent had approved Covidex as a supportive drug in management of viral infections and it had authorised the 2nd respondent to produce, sell and distribute Covidex which company is not the rightful owner or holder of the patent of the drug.

5. That on 5th day of July 2021, Professor Ogwang Patrick the founder of the 2nd respondent addressed a press conference disregarding the claims of Mbarara University and confirmed that the 2nd respondent will continue to produce and sell covidex to the public through its agents.

6. That Dr. Ogwang is employed by Mbarara University and was recently promoted to the rank of associate professor in the pharmacy Department.

7. That where an invention is made by an employee in execution or not in execution of an employment contract, and where for making that invention the employee used materials and data know-how of the employer, the right to the patent belongs to the employer.

8. That the action of the 1st respondent to grant the 2nd respondent the right to produce, sell and distribute covidex yet it is not the rightful owner of the patent was not only illegal, procedurally improper, irrational, unconscionable, malafide and unjustifiable but also prejudicial to public interests.

9. That a memorandum of understanding was signed and it shows that Mbarara University of Science and Technology received Ugx. Shs. 283,312,000 under grant No. MoST/NRRIP/2020/005 to research on covidex medicine and the said grant is a loan from World Bank to be paid by Ugandans.

10. That unless court intervenes, Mbarara university , the government, the tax payers and the public at large are going to lose as private gains from the patent is going to be more prominent than the indebted social good.

The respondents opposed his application and the 1st respondent filed an affidavit in reply through David Nahamya the Secretary of the 1st respondent and the 2nd respondent filed an affidavit in reply through *Dr. Ogwang Patrick Engeu*, the Director of the 2nd respondent.

1. That the applicants do not have *locus standi* or protectable interest in law to bring this application for orders of Judicial Review and are not affected by the decision of the 1st respondent.

2. That the application lacks merit and is brought malafide with ill intentions to frustrate the production of a lifesaving drug Covidex.

3. That Covidex was developed at Jena Herbals Uganda Ltd under the leadership of Dr. Ogwang the Director of the 2nd respondent and was never developed at Mbarara University of Science and Technology.

4. That the 2nd respondent is not responsible for the skyrocketing prices of Covidex drug and the 2nd respondent cannot be held responsible for the actions of the said greedy individuals.

5. That the 1st respondent gave the 2nd respondent a hearing before Covidex was approved and to date, Mbarara University of Science and Technology has not written to the 1st respondent to challenge the same.

6. That the 2nd applicant has never furnished the 1st respondent with documentary evidence that it developed or invented Covidex.

7. That the 1st respondent was neither a party nor privy to the grant agreement dated 12th January 2021 between Ministry of science, technology and innovation and Mbarara University of Science and Technology Pharm-Biotechnology and Traditional Medicine Center on which the applicant's grievance is premised and cannot therefore be adjudged to have acted in breach of the terms and conditions thereof or in bad faith.

8. That the 1st applicant has no right to recommend or dictate the price of Covidex at Ug. Shs 3,000 as nobody has a right to do so in a free and fair economy.

9. That the 2nd respondent has no intentions of making a big deal of money out of Covidex drug but is well intentional to save lives of people from the deadly ravaging covid-19 disease that has claimed many lives in the world.

10. That the applicants have not given any justifiable reasons for stopping the 2nd respondent from producing the Covidex drug save for the idle talk of undermining the inventor of Covidex, the 2nd respondent.

11. That the 1st respondent rightly approved the drug for use and does not approve products for distribution or sale of drugs and the 1st respondent's statutory mandate does not include granting patents or determining ownership of intellectual property rights.

12. That the 2nd respondent company is the only one that produces, distributes and sells Covidex drug a clear implication that no one else is claiming the same.

Issues for determination

1. ***Whether the application is competently before the court?***
2. ***Whether the 1st respondent properly granted permission to the 2nd respondent to produce, sell and distribute covidex drug.***

3. ***What remedies are available?***

At the hearing the applicants were represented by *Counsel Jude Mbabali* and the 1st respondent was represented by *Counsel Katusiime Leliah* and the 2nd respondent by *Counsel Omongole Richard*.

Both counsel filed written submissions which this court has considered in this matter.

The parties raised preliminary objections which in my view should have be addressed through the first issue and I have not wasted time on them.

Whether the application is competently before the court?

The 2nd respondent's counsel contended that the applicants do not have locus standi to bring this application. Counsel for the 2nd respondent argued that the applicants have not demonstrated how their rights or anybody's rights have been violated and that Mbarara University of Science and Technology withdrew any claim and would have been a party with locus.

Counsel for the applicants in reply argued that the 1st applicant is an incorporated public interest pressure group whose main objectives are; to promote respect for human rights, constitutionalism, rule of law and governance in Uganda, engage in public interest litigation and actively participate in matters of public accountability, transparency and adherence to the rule of law, and is closed with sufficient interest in intellectual property and copy rights of public institutions.

Analysis

The question this court has to consider is whether the applicant has sufficient interest in instituting this application for judicial review or is a mere busy body. The task of the court in assessing whether a particular claimant has standing is a balancing act between the various factors.

Sufficient interest is a standard which could sufficiently embrace all classes of those who might apply and yet permit sufficient flexibility in any particular case to determine whether or not 'sufficient interest' was in fact shown.

Rule 3A of the *Judicature (Judicial Review) (Amendment) Rules, 2019* provides that;
Any person who has direct or sufficient interest in a matter may apply for judicial review

The court is duty bound to determine the issue of *locus standi* since our rules of procedure removed the application for leave to apply for judicial review which was a sieving stage of frivolous applications which would never proceed to be filed in court. The permission/leave stage was a good check for hopeless cases and would avoid claimants who are simply meddlers or busy bodies. The preliminary evaluation of standing at permission stage enabled the court to prevent abuse by busybodies, cranks and other mischief-makers.

The standard of sufficiency has been relaxed in recent years, the need to have an interest has remained and that the fact that…..a sufficient interest [is required] undoubtedly shows that not every applicant is entitled to judicial review as of right. It is important that the courts do not by use or misuse of the weapon of judicial review cross that clear boundary between what is administration, whether it be good or bad administration, and what is an unlawful performance of the statutory duty by a body charged with performance of that duty. See ***R v Inland revenue Commissioners, ex parte National Federation of Self-Employed and Small Businesses Ltd [1982]AC 617.***

The law is equally concerned with 'representative standing' which involves associational standing which claims on behalf of (interests of) identifiable individuals who are its members or whom it claims to represent; and public interest standing, which involves an individual, corporation or

group purporting to represent "the public interest" rather than the interests of any identified or identifiable individuals. The court would probe in any detail the relationship between the claimant and the class they claim to represent.

The affidavit in support by the 1st applicant states that it is an incorporated public interest pressure group main objectives are; to promote respect for human rights, constitutionalism, rule of law and governance in Uganda, engage in public interest litigation and actively participate in matters of public accountability, transparency and adherence to the rule of law closed with sufficient interest in intellectual property and copyrights of public institutions.

It is equally not clear whether the 1st applicant is company limited by guarantee or a Nongovernmental Organisation with licence to operate as such. The documents of incorporation are not attached and this leaves this court with no evidence to discern the true status of the 1st applicant. The 1st applicant contends that it is closed with sufficient interest in intellectual property and copyrights in public institutions which in my view is more confusing in relation to its core objectives.

Secondly, the 2nd applicant states that he is a male adult Ugandan of sound mind, a journalist, former Secretary for works and councilor at Bukomasimbi District, a resident of Masaka City. The above description of the 2nd applicant fall far short of showing any sufficient interest in making of the Covidex drug by the 2nd respondent.

He does not state what interest he possesses to lead him to file this application for judicial review. The threshold for instituting an application for judicial review is to show sufficient interest in an application in order to be allowed access to the temple of justice. This would enable the court assess the level of grievance against what is being challenged and to sieve out hopeless applications.

The interest required by law is not a subjective one; the court is not concerned with the intensity of the applicant's feelings of indignation at the alleged illegal action, but with objectively defined interest. Strong feelings will not suffice on their own although any interest may be accompanied by sentimental considerations. Every litigant who approaches the court, must come forward not only with clean hands but with clean mind, clean heart and with clean objective.

In particular, a citizen's concern with legality of governmental action is not regarded as an interest that is worth protecting in itself. The complainant (applicant/petitioner) must be able to point to something beyond mere concern with legality: either a right or to a factual interest. Judicial review applications should be more restrictive to persons with direct and sufficient interest and should not be turned into class actions or *actio popularis* which allow any person to bring an action to defend someone else's interest/rights under Article 50 of the Constitution. See ***Community Justice and Anti-Corruption Forum v Law Council & Sebalu and Lule Advocates High Court Miscellaneous Cause No. 338 of 2020***

The court should attach importance to a track record of concern and activity by the applicant in relation to the area of government decision-making body under challenge. Standing in judicial review matters should remain a matter of judicial discretion contingent on a range of factors identified in that decision, for the most part, those factors do not operate to prevent worthy public interest cases being litigated: is there a justiciable issue? Is the applicant raising a serious issue? Does the applicant have genuine interest in the matter? Is this a reasonable and effective setting for the litigation of issues?

In any legal system that is strained with resources, professional litigant and meddlesome interloper who invoke the jurisdiction of the court in matters

that do not concern them must be discouraged. An applicant will have standing to sustain public action only if he fulfills one of the two following qualifications: he must either convince the court that the direction of law has such a real public significance that it involves a public right and an injury to the public interest or he must establish that he has a sufficient interest of his own over and above the general interest of other members of the public bringing the action.

It is the duty of the courts to protect the scarce state resources and the over-burdened court system by ensuring that litigants who appear in court in matters of judicial review have a direct or sufficient interest to come to court. Precious resources would be wasted on the adjudication and defence of claims if mere busybodies could challenge every minor or alleged minor infraction by the state or public officials. Without sufficient interest threshold for standing the floodgates will open, inundating the courts with vexatious litigation and unnecessary court disputes.

The protection of the rule of law does not require that every allegation of unlawful conduct by a public authority must be examined by court….there must be considerations which lead the court to treat the applicant as having an interest which is sufficient to justify his bringing the application before the court.

Thus, there are limits on public interest standing and these limits operate in the light of policy concerns such as the court being flooded with claims, or authorities being harassed with vexatious review challenges. The court will assess the sufficient interest against all the factual and legal circumstances of the case. It is a mixed question of fact and degree. The court is at loss as to what the applicants' interest was in bringing this matter or whether it was a case of *'publicity litigation'* to be relevant in the covid-19 pandemic period.

The applicants for reasons herein stated lacked standing or *locus standi* in this matter and this would render the application incompetent.

Secondly, the applicants have come to this court challenging the decision of National Drug Authority (1st respondent) issuing and granting the 2nd respondent (Jena Herbals Uganda Ltd) permission to produce and distribute Covidex drug.

The main issue and concern of the applicants if they had had *locus standi* would have been about intellectual property rights in the Covidex drug. This would have been a dispute that concerns patent or copyrights dispute which would be addressed through other available legal redress rather than judicial review.

In addition, the mandate of the 1st respondent is to among others; to control the importation, exportation and sale of pharmaceuticals; control the quality of drugs; promote and control local production of essential drugs and encourage research and development of herbal medicines. The authority is not concerned with patent rights and it was not concerned with determining whether the 2nd respondent or Mbarara University of Science and Technology owned the intellectual property rights in Covidex.

The applicants complaint is judicial review is totally misplaced and misconceived against the 1st respondent as the regulator national drugs. Hon. Kasibante contends that the application is challenging the illegal and wrong procedure the 1st respondent used to arrive at the decision to allow the 2nd respondent to distribute covidex. That the 1st respondent did not carry out clinical trials on the covidex medicine before authorizing the 2nd respondent to sell, distribute and produce the drug.

The applicants are mere busybodies with lack of expertise to challenge the drug making process and subjecting the same to challenge in judicial review procedure. The 1st applicant is a public interest pressure group whose concern is about human rights, constitutionalism, rule of law and governance in Uganda. The core objectives are totally off what they are challenging in this court and this may explain why they have mixed up the drug production with human rights and rule of law. It may be deduced from the facts and circumstances that the applicants were *'hired guns'* to frustrate the Assoc. Prof Patrick Ogwang's (2nd respondent) efforts and prominence in the fight against Covid-19 pandemic.

Mbarara University of Science and Technology Council in September 2021 conceded and confirmed that the PHARMBIOTRAC does not possess the formula of the 3 herbal products including covidex under research and further that it is Jena Herbal (U) Ltd which holds the copyright. The committee arrived at a conclusion that covidex originated from Jena Herbals and it was in existence before the implementation of the research grant between Ministry of Science and Mbarara University of Science and Technology and that many government departments have also accorded Jena Herbals Uganda Ltd national recognition as the inventors and owners of Covidex.

This settled the dispute as to the ownership of the patent or copyrights in covidex and the applicants would have no basis to re-litigate the same on behalf of Mbarara University of Science and Technology which would have been the body with direct and sufficient interest to challenge the 2nd respondent.

It therefore suffices to say that what the applicants are claiming are private rights as to who owns the intellectual property rights of Covidex or whether it followed the proper procedures for it to be produced which

claim does not fall under the ambit of the principles for judicial review but rather private rights which should have been claimed for by way of the ordinary way of procedure under the available legal regime.

The application for this reason would also have failed and would have been dismissed accordingly.

This application stands dismissed with costs to the respondents.

SSEKAANA MUSA
JUDGE
17TH MARCH 2023